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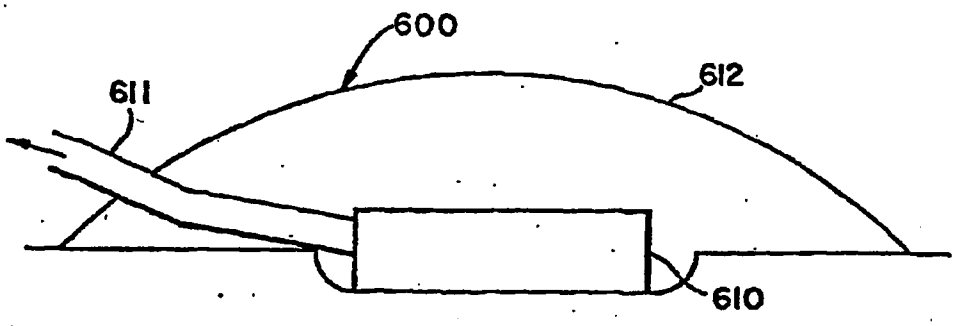


(57) Abstract

A method of treating tissue damage comprises applying a negative pressure to a wound sufficient in time and magnitude to promote tissue migration and thus facilitate closure of the wound. The method is applicable to wounds, burns, infected wounds, and live tissue attachments. A wound treatment apparatus (600) is provided in which a fluid impermeable wound cover (612) is sealed over a wound site. A screen (610) in the form of an open cell foam screen or a rigid porous screen is placed beneath the wound cover (612) over the wound. A vacuum pump supplies suction within the wound cover (612) over the treatment site.

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# Wound Treatment Employing Reduced Pressure

## Field of the Invention

The present invention relates to an apparatus and method for treating a wound by applying reduced pressure to the wound.

## Background of the Invention

The treatment of open wounds that are too large to spontaneously close has long been a troublesome area of medical practice. Closure of an open wound requires inward migration of surrounding epithelial and subcutaneous tissue. Some wounds, however, are sufficiently large or infected that they are unable to heal spontaneously. In such instances, a zone of stasis in which localized edema restricts the flow of blood to the epithelial and subcutaneous tissue forms near the surface of the wound. Without sufficient blood flow, the wound is unable to successfully fight bacterial infection and is accordingly unable to close spontaneously.

An initial stage of wound healing is characterized by the formation of granulation tissue which is a matrix of collagen, fibronectin, and hyaluronic acid carrying macrophages, fibroblasts, and neovasculature that forms the basis for subsequent epithelialization of the wound. Infection and poor vascularization hinder the formation of granulation tissue within wounded tissue, thereby inhibiting wound healing. It therefore becomes desirable to provide a

technique for increasing blood circulation within wounded tissue to promote spontaneous healing and to reduce infection.

Poor blood circulation and infection at the wound may also hinder attachment of skin grafts or flaps upon wounded tissue. Skin grafts and flaps will not attach to tissue that is poorly vascularized, infected or necrotic. However, grafts and flaps can be used with much greater success on tissue that, although wounded, is able to form granulation tissue. Accordingly, a technique for promoting blood circulation at the wounded tissue would also promote successful attachment, or "take," of skin grafts or flaps to the wounded tissue as a consequence of increased blood circulation within the grafts or flaps.

Another problem encountered during the treatment of wounds is the selection of an appropriate technique for wound closure during the healing process. Sutures are often used to apply force to adjacent viable tissue in order to induce the edges of a wound to migrate together and heal. However, sutures apply a closure force to only a very small percentage of the area surrounding a wound. When there is scarring, edema, or insufficient tissue, the tension produced by the sutures can become great causing excessive pressure to be exerted by the sutures upon the tissue adjacent to each suture. As a result, the adjacent tissue often becomes ischemic thereby rendering suturing of large wounds counterproductive. If the quantity or size of the sutures is increased to reduce the tension required of any single suture, the quantity of foreign material within the wound is concomitantly increased and the wound is more apt to become infected. Additionally, the size or type of a

particular wound may prevent the use of sutures to promote wound closure. It therefore becomes desirable to provide an apparatus and method for closing a large wound that distributes a closure force evenly about the periphery of the wound.

Wounds resulting from ischemia, or lack of blood flow, are also often difficult to heal since decreased blood flow to a wound may inhibit normal immune reaction to fight infection. Patients that are bedridden or otherwise non-ambulatory are susceptible to such ischemic wounds as decubitus ulcers or pressure sores. Decubitus ulcers form as a result of constant compression of the skin surface and underlying tissue thus restricting circulation. Since the patient is often unable to feel the wound or to move sufficiently to relieve the pressure, such wounds can become self-perpetuating. Although it is common to treat such wounds with flaps, the conditions that initially caused the wound may also work against successful flap attachment. Wheelchair-bound paraplegics, for example, must still remain seated after treatment of pelvic pressure sores. It therefore becomes desirable to provide a treatment procedure for ischemic wounds that can be conducted in situ upon an immobile or partially mobile patient.

Other types of wounds in which ischemia leads to progressive deterioration include partial thickness burns. A partial thickness burn is a burn in which the cell death due to thermal trauma does not extend below the deepest epidermal structures such as hair follicles, sweat glands, or sebaceous glands. The progression of partial thickness burns to deeper burns is a major problem in burn therapy. The ability to control or diminish the depth of burns greatly enhances the prognosis for burn patients and decreases

morbidity resulting from burns. Partial thickness burns are formed of a zone of coagulation, which encompasses tissue killed by thermal injury, and a zone of stasis. The zone of stasis is a layer of tissue immediately beneath the zone of coagulation. Cells within the zone of stasis are viable, but the blood flow is static because of collapse of vascular structures due to localized edema. Unless blood flow is re-established within the zone of stasis soon after injury, the tissue within the zone of stasis also dies. The death of tissue within the zone of stasis is caused by lack of oxygen and nutrients, reperfusion injury (re-establishment of blood flow after prolonged ischemia), and decreased migration of white blood cells to the zone resulting in bacterial proliferation. Again, it becomes desirable to provide a technique for treating burn wounds by enhancing blood circulation to the wounded tissue to inhibit burn penetration.

Summary of the Invention

In accordance with the present invention a wound treatment apparatus is provided for treating a wound by applying reduced pressure (i.e. pressure that is below ambient atmospheric pressure) to the wound in a controlled manner for a selected time period. The application of reduced pressure to a wound provides such benefits as faster healing, increased formation of granulation tissue, closure of chronic open wounds, reduction of bacterial density within wounds, inhibition of burn penetration, and enhancement of flap and graft attachment. Wounds that have exhibited positive response to treatment by the application of negative pressure include infected open wounds, decubitus ulcers, dehisced incisions, partial

thickness burns, and various lesions to which flaps or grafts have been attached.

The wound treatment apparatus in accordance with the present invention includes a reduced pressure application appliance which is applied to a treatment site at which there is a wound and normal tissue surrounding the wound. The reduced pressure application appliance includes a fluid impermeable wound cover for covering and enclosing the wound. The appliance also includes sealing means for sealing the wound cover to the surrounding tissue of the wound in order to maintain reduced pressure in the vicinity of the wound during wound treatment. When the wound cover is sealed in position over the wound site, a generally fluid-tight or gas-tight sealed enclosure is formed over the wound site. The sealing means may be in the form of an adhesive applied to the underside of the wound cover for sealing the wound cover around the periphery of the wound. The sealing means may also include a separate sealing member such as an adhesive strip or a sealing ring in the form of a tubular pad or inflatable cuff secured to the wound cover for positioning around the periphery of the wound. In selected embodiments, the reduced pressure within the sealed enclosure under the wound cover may serve to seal the wound cover in position at the wound site. The reduced pressure appliance also includes a suction port for supplying reduced pressure within the sealed volume enclosed beneath the wound cover. The suction port may be in the form of a nipple on the wound cover. Alternatively, the suction port may be in the form of a tube attached to the wound cover or provided as a feedthrough beneath the wound cover. The appliance may also include a porous wound screen for placement in the wound or in position overlying the

wound in order to prevent overgrowth of wound tissue during treatment. The wound screen is sufficiently porous to permit gas flow to the wound. The porous wound screen may be in the form of a sponge or open-cell foam material for placement in the wound. The porous screen may also include a rigid or semi-rigid screen for overlying the wound.

A vacuum system is connected with the reduced pressure appliance in order to provide suction or reduced pressure to the appliance. For this purpose, the vacuum system includes a suction pump or suction device for connection with the suction port of the appliance for producing the reduced pressure over the wound site. The vacuum system may include a section of hose or tube, such as a vacuum hose, that interconnects the suction device with the suction port of the appliance to provide the reduced pressure at the wound site. A collection device in the form of a fluid trap may be provided intermediate the vacuum hose of the suction device and the suction port of the appliance to trap any exudate which may be aspirated from the wound by the negative pressure appliance. A stop mechanism may also be provided for the vacuum system to halt production of the reduced pressure at the wound site in the event that an excessive quantity of exudate has been collected. The apparatus may also include a control device for controlling the pump and for providing intermittent or cyclic production of reduced pressure.

In a particular embodiment of the invention, the wound cover for the reduced pressure appliance may be in the form of a gas impermeable covering sheet of flexible polymer material, such as polyethylene, having an adhesive backing that provides the seal for securing the sheet over the wound site to provide an

gas-tight or fluid-tight sealed enclosure over the wound site. The vacuum system of the wound treatment apparatus may include a suction pump having a vacuum hose that is connected with a suction tube serving as a suction port for the appliance. The suction tube for the appliance runs beneath the cover sheet that is sealed in position over the wound site and into the fluid-tight enclosure provided under the cover sheet. An adhesive backing on the cover sheet is used to provide a fluid-tight seal around the feedthrough for the suction tube at the wound site. Within the enclosure, the suction tube is connected with a piece of open-cell foam for placement in the wound. The open-cell foam functions to more uniformly apply reduced pressure or suction over the wound site while holding the cover sheet substantially out of the wound during the application of reduced pressure at the enclosed wound site.

In operation, a method of treating tissue damage is provided which comprises applying a negative or reduced pressure to a wound over an area sufficient to promote the migration of epithelial and subcutaneous tissue toward the wound and for a time period sufficient to facilitate closure of the wound. The method is useful for treating pressure sores.

A method of treating a burn wound is also provided which comprises applying a negative or reduced pressure to the burn over an area and for a time sufficient to inhibit progression in the depth of the burn. The method is useful on a partial thickness burn soon after its infliction.

A method of treating tissue damage is also provided which comprises applying a negative or reduced pressure to a wound for a time sufficient to reduce bacterial density in the wound. One use of

this method is its application to a wound for a selected time period such as at least three days to reduce the bacterial density of an infected wound to the point at which surgical closure can be attempted.

Another aspect of the invention is a method of enhancing the attachment of adjacent tissue to a wound which comprises applying negative or reduced pressure to a joined complex of the adjacent living tissue and the wound at a sufficient magnitude of reduced pressure and for a sufficient time duration to promote the migration of epithelial and subcutaneous tissue toward the complex. This method enhances attachment of adjacent tissue to tissues of the wound edges. Another use of this method is to enhance attachment of an open skin graft to the wound tissue.

Brief Description of the Drawings

The foregoing summary, as well as the following detailed description of the preferred embodiments of the present invention, will be better understood when read in conjunction with the appended drawings, in which:

FIG. 1 is a schematic elevational view of a wound treatment apparatus in accordance with the present invention in which a reduced pressure appliance, shown in partial section, includes a flexible, fluid impermeable wound cover sealed over the wound and a foam wound screen positioned in the wound, and in which a vacuum system provides reduced pressure within the wound cover of the appliance;

FIG. 2 is a schematic sectional elevational view of a reduced pressure appliance in accordance with another embodiment of the present invention having a rigid, fluid impermeable wound cover sealed over a

wound and a rigid or semi-rigid screen overlying the wound;

FIG. 3 is a schematic sectional elevational view of a reduced pressure appliance in accordance with another embodiment of the present invention having a rigid, fluid impermeable wound cover sealed over a wound;

FIG. 4 is a schematic sectional elevational view of a reduced pressure appliance in accordance with another embodiment of the present invention having a semi-rigid, fluid impermeable cover enclosing a wound and a rigid or semi-rigid screen overlying the wound, with an overlying flexible fluid impermeable cover sheet sealing the enclosure over the wound;

FIG. 5 is a schematic elevational view of a reduced pressure appliance, shown in partial section, in accordance with another embodiment of the present invention having a flexible, fluid impermeable wound cover over an inner rigid porous support cup;

FIG. 6 is a schematic elevational view of a reduced pressure appliance, shown in partial section, having a rigid outer frame with support legs for supporting a flexible, fluid impermeable sealing cover over a wound;

FIG. 7 is a schematic elevational view in partial section of an alternative fluid collection device having a float valve for use in the vacuum system of FIG. 1;

FIG. 8 is a schematic view of an alternative vacuum system;

FIG. 9 is a schematic view of an alternative vacuum system incorporating a fluid collection device having an actuator for de-activating the vacuum system upon collection of a predetermined quantity of fluid;

FIG. 10 is a schematic cross-sectional view of a reduced or negative pressure appliance comprising an open-cell polymer foam screen, a flexible hose for connecting the foam screen with a vacuum system, and an adhesive-backed flexible polymer sheet overlying the foam-hose assembly to provide a seal over a wound; and

FIG. 11 is a schematic cross-sectional view of a reduced or negative pressure appliance comprising a rigid porous screen for a wound, a rigid or semi-rigid cup for covering the wound having an inflatable cuff attached about the base of the cup, and a flexible hose extending from the cup for connection with a vacuum system.

Detailed Description of the Preferred Embodiments

In accordance with the present invention, a wound treatment apparatus is provided for treating a wound by application of reduced pressure (i.e., below atmospheric pressure) so that suction may be applied to a wound site in a controlled manner for a selected time period. As schematically shown in Fig. 10, a wound treatment apparatus includes a reduced pressure appliance, generally designated 600, which is applied to a wound site to treat the wound through the application of reduced pressure. The appliance 600 is sealed in position over the wound site to create a generally fluid-tight or gas-tight enclosure over the wound site.

The appliance 600 includes a substantially flat section of open cell polyester foam section 610 (Fischer Scientific, Pittsburgh, PA 15219) sufficiently large to cover the wound and thus prevent wound overgrowth, a flexible hollow tube 611 (Fischer Scientific) inserted into the open cell foam section

610 and joined thereto with an adhesive and extending to attach at its opposite end with a Gast Vacuum pump (Fischer Scientific), and an Ioban adhesive sheet 612 (Minnesota Mining and Manufacturing, St. Paul, MN 55144) overlying the foam section 610 and tubing 611 and adhered to the skin surrounding the wound, thus forming a seal that allows creation of a vacuum when the suction pump operates. Such an appliance 600 would most preferably be packaged in a sterile condition to ameliorate the need for sterilization of the apparatus prior to use. The adhesive sheet 612 may be packaged separately from the foam-tube assembly 610 and 611. A particular advantage of this configuration is its use with pressure sores because the device can be placed in the depths of the wound and the patient can lie upon the device without either affecting the utility of the device or further damaging the wound. This becomes critical if the patient cannot be moved from this posture for medical or other reasons.

As shown in FIG. 11, a reduced pressure appliance, generally designated 615, in accordance with another embodiment of the present invention, is schematically depicted. The reduced pressure appliance 615 includes an adult CPR mask 620 (Doug Brown and Associates, Huntington Beach, CA 92648) comprising a rigid or semi-rigid fluid impermeable cup 621 having an inflatable cuff 622 mounted around the periphery of the base of the cup 622 for contact with the skin, an open cell polyester screen 624 overlying the wound, and a flexible 1/4 inch diameter hose 623 (Fischer Scientific) connected by a Nalgene tubing connector extending through a sealed hole in the cup for connection with a vacuum pump (Fischer Scientific). The hose 623 is connected with the pump

40 of a vacuum system 30 of the type shown in FIG. 1 to provide reduced pressure within the cup 621. The vacuum created within the cup 621 by the vacuum system may be sufficient to seal the cup in position over the wound site. Alternatively, fluid impermeable adhesive covering or strips may also be used to seal the appliance 615 in proper position.

Referring to FIG. 1, a wound treatment apparatus, generally designated 25, is depicted having a reduced pressure appliance 29 for enclosing a wound site to provide a fluid-tight or gas-tight enclosure over the wound site to effect treatment of a wound 24 with reduced or negative pressure. The wound treatment apparatus 25 includes a reduced pressure appliance, generally designated 29, which is applied to and sealed over a wound site in order to enclose the wound site for treatment with suction or reduced pressure within a sealed generally fluid-tight or gas-tight enclosure. For the purpose of creating suction within the appliance 29, the appliance 29 is connected with a vacuum system, generally designed 30, to provide a source of suction or reduced pressure for the sealed appliance 29 at the wound site. The appliance 29 includes a fluid-impermeable wound cover 18 in the form of a flexible, adhesive, fluid impermeable polymer sheet for covering and enclosing the wound 24 and the surrounding normal skin 22 at the wound site. The wound cover 18 includes an adhesive backing 20 which functions to seal the wound cover to the normal skin 22 around the periphery of wound 24 to provide a generally gas-tight or fluid-tight enclosure over the wound 24. The adhesive cover sheet 18 must have sufficient adhesion to form a fluid-tight or gas-tight seal 19 around the periphery of the wound and to hold the sheet 18 in sealed contact with the skin during

the application of suction or reduced or negative pressure.

The appliance 29 also includes a porous wound screen 10 which is placed within the wound 24. The wound screen 10 is placed over substantially the expanse of the wound to prevent its overgrowth. The size and configuration of the wound screen 10 can be adjusted to fit the individual wound. It can be formed from a variety of porous materials. The material should be sufficiently porous to allow oxygen to reach the wound. The wound screen 610 may be in the form of an open-cell polymer foam, such as a polyurethane foam, which is sufficiently porous to allow gas flow to and/or from the wound 24. Foams may be used that vary in thickness and rigidity, although it may be desirable to use a spongy material for the patient's comfort if the patient must lie upon the appliance during treatment. The foam may also be perforated to enhance gas flow and to reduce the weight of the appliance. As shown in FIG. 1, the screen 10 is cut to an appropriate shape and size to fit within the wound 24. Alternatively, the screen may be sufficiently large to overlap the surrounding skin 22.

The appliance 29 also includes a suction port in the form of a hollow suction tube 12 that connects with the vacuum system 30 to provide suction within the sealed enclosure. The suction tubing 12 serves as a suction port for appliance 29. An end segment 12a of the tubing 12 is embedded within the foam screen 10 for providing suction or reduced pressure within the enclosure provided under the wound cover 18. Embedding the open end of segment 12a of tubing 12 within the interior of the foam screen 10 permits the foam screen 10 to function as a shield to help prevent

the wound cover 18 from being inadvertently sucked into sealing engagement with the open end of the tube thereby plugging the tube 12 and restricting gas flow. The tube segment 12a embedded within the foam screen 10 preferably has at least one side port 14 for positioning within the interior of the foam screen 10 to promote substantially uniform application of reduced pressure throughout the enclosure. Positioning the side port 14 of tube segment 12a within the interior of the foam screen 10 permits the foam screen 10 to function as a shield for the side port to thereby prevent the wound cover 18 from being sucked into the side port 14 and thereby restricting gas flow. The open cells of the foam screen 10 facilitate gas flow throughout the enclosure. In addition, the foam screen 10 functions to prevent wound overgrowth and to hold the wound cover 18 generally out of contact with the wound 24 during the application of suction within the enclosure.

Tubing 12 and tube segment 12a are sufficiently flexible to permit movement of the tubing but are sufficiently rigid to resist constriction when reduced pressure is supplied to the appliance 29 or when the location of the wound is such that the patient must sit or lie upon the tubing 12 or upon the reduced pressure appliance 29. The screen-tube assembly comprising the foam screen 10 and the tube 12 may be fabricated by snaking the end of the tube segment 12a through an internal passageway in the foam screen 10 such as by pulling the end of the tube segment 12a through the passageway using forceps. Alternatively, fabrication of the screen-tube assembly may be accomplished by suspending the end of the tube segment 12a into a suitable mold or form and then blowing foam into the mold or form to embed the tube end segment

12a within the blow-molded foam screen. The screen-tube assembly 12 and 10 is preferably prepared prior to use under sterile conditions and then stored in an aseptic package.

In order to use the reduced pressure appliance 29 at the site of the wound 24, the flexible, gas-impermeable, adhesive wound cover sheet 18 is secured in position at the wound site overlying the foam screen 10 disposed within the wound 24. The wound cover sheet 18 is secured and sealed to the surrounding normal skin 22 by an adhesive layer 20 on the under surface of the wound cover 18 to form a gas-tight seal 19 around the periphery of the wound 24. The wound cover 18 also provides a gas-tight seal around the tubing 12 at the feedthrough location 22a where the tubing 12 emerges from beneath the wound cover 18. The wound cover 18 is preferably formed of a fluid impermeable or gas impermeable flexible adhesive sheet such as Ioban, a product of the 3M corporation of Minneapolis, Minn.

The vacuum system 30 includes a suction pump 40 that produces a source of reduced pressure or suction which is supplied to the reduced pressure appliance 29 by suction tubing 12. As shown in FIG. 1, a fluid trap, generally designated 28, is interconnected between the suction pump 40 and the appliance 29 to remove and collect any exudate which may be aspirated from the wound 24 by the reduced pressure appliance. The appliance 29 functions to actively draw fluid or exudate from the wound 24. Collection of exudate in a fluid trap 28 intermediate the pump 40 and the appliance 29 is desirable to prevent clogging of the pump 40. A suitable fluid trap 28 may be assembled from an Erlenmeyer or side-arm flask 31 having a top opening and a side-arm opening. The fluid trap 28

includes a first port 32 at the top opening of the flask for sealed connection to suction tubing 12. The first port 32 enables suction to be applied to the reduced pressure appliance 29 through the tubing 12 and also enables exudate from the wound covered by reduced pressure appliance 29 to be drained into the flask 31. The flask 31 provides a collecting vessel 33 for the fluid trap for containing and temporarily storing the collected exudate. A suction port 34 is provided at the side-arm opening of the flask to enable the application of suction from vacuum pump 40. The suction port 34 of the fluid trap 28 is connected to the vacuum pump 40 by vacuum line 36. The fluid trap 28 is sealed generally gas-tight to enable the suction pump 40 to supply suction to the appliance 29 through the fluid trap 28. A filter 38 such as micropore filter is preferably attached to the exhaust of the pump 40 to prevent potentially pathogenic microbes or aerosols from being vented to atmosphere by the vacuum pump 40.

Predetermined amounts of suction or reduced pressure are produced by the vacuum pump 40. The vacuum pump 40 is preferably controlled by a control device 44 such as a switch or a timer which may be set to provide cyclic on/off operation of the vacuum pump 40 according to user-selected intervals. Alternatively, the vacuum pump 40 may be operated continuously without the use of a cyclical timer.

The vacuum system 30 preferably includes a shut-off mechanism for halting or inhibiting the supply of the reduced pressure to the appliance 29 in the event that the exudate aspirated from the wound 24 exceeds a predetermined quantity. Interrupting the application of suction to the appliance 29 is desirable to prevent exsanguination in the unlikely event a blood vessel

ruptures under the wound cover 18 during treatment. If, for example, a blood vessel ruptures in the vicinity of the wound 24, a shut-off mechanism would be useful to prevent the vacuum system 30 from aspirating any significant quantity of blood from the patient. As a safety feature, various mechanical or electrical detection mechanisms may be employed to detect the level of exudate in the fluid trap 28.

As shown in FIG. 7, a fluid trap 28 employing a collection bottle or flask 35 is provided for connection intermediate the pump 40 and the appliance 29 for collecting exudate from the wound site. The flask 35 has a side-arm port 43 connected to suction tube 12 leading to the reduced pressure appliance 29 and a suction port 34 located at the top 44 of the flask 35 connected to the vacuum hose 36 leading to the vacuum pump 40. For the purpose of detecting liquid level within the flask 35, a float valve assembly, generally designated 39, is provided. The float-valve assembly 39 functions to close and seal off the suction port 34 of the fluid trap 28 when the quantity of exudate in the collecting vessel 33 exceeds a predetermined quantity. The float valve assembly 39 is provided in the form of a ball 46 which is held and suspended within a cage 47 positioned below a valve seat 48 disposed within the opening at the top 44 of the flask 35. The ball 46 has a specific gravity below that of the exudate so that the ball 46 will float upon the exudate and will be lifted against the valve seat 48 as the vessel 33 fills with exudate. When the ball 46 is firmly seated against the valve seat 48, the float valve 39 blocks suction port 34 and thereby shuts off the source of suction from vacuum line 36. The suction within the appliance 29 at the wound site arrests thus halting the

aspiration of exudate from the wound.

Other types of mechanisms may be employed to detect the liquid level within the fluid trap 28 in order to arrest operation of the vacuum source. An alternative vacuum system 30a is shown in FIG. 8 in which a filter 38a is employed in vacuum line 36 for filtering the fluid or gas flow through the vacuum line 36 and for detecting the level of liquid in fluid trap 28. Exudate from the wound is collected in vessel 33. When the vessel 33 becomes full, aspiration of further exudate from the wound causes the vacuum line 36 to begin to collect exudate which eventually reaches the in-line filter 38a positioned in the vacuum line 36 intermediate the fluid trap 28 and the pump 40a having operational control 44a. The filter 38a contains a filter element that is selected to clog when exposed to sufficient amounts of moisture to thereby halt the supply of suction through the fluid trap 28 to the appliance 29. The filter 38a is preferably an in-line, disc-shaped submicron filter having a nitrocellulose or PTFE filtration element for filtering particles larger than about .1$\mu$m from the vacuum line 36. In addition to preventing excess fluid aspiration, the filter 38a in the vacuum line 36 prevents contamination of the vacuum pump 40 by filtering potentially pathogenic microbes and aerosols.

Other types of detection devices may also be employed to detect a predetermined level of liquid collected in collection vessel 33. For example, collection of exudate in excess of a predetermined quantity may enable actuation of an electronic switch which turns off the vacuum pump or otherwise halts the supply of suction to the reduced pressure appliance 29. Referring to FIG. 9, the suction tubing 12 from

the reduced pressure appliance 29 is connected to a three-port coupling device 160 that interconnects suction tube 12, vacuum line 36b and fluid collecting apparatus 131. The coupling device 160 permits transmission of suction from the vacuum line 36b of the pump 40b to the suction tubing 12. The coupling device 160 also permits aspirated exudate from tubing 12 to be collected in an expandable container, such as an intravenous fluid bag 162, housed beneath the coupling device 160 in a rigid housing vessel 33b. As exudate is collected, the bag 162 expands to conform to the shape of the interior surface of the surrounding rigid vessel 33b. An actuator 166, such as a spring-loaded actuator switch, is located within the side wall of the rigid vessel 33b and functions to shut off the pump 40b upon actuation of the switch 166. When the bag 162 expands sufficiently to contact and actuate switch 166 as shown in dashed lines at 162a in FIG. 9, the switch 166 is opened and the supply of power to the pump 40b along power line 164 is interrupted and the supply of suction to the appliance 29 is stopped. The actuator switch 166 may also cooperate with control 44b for the pump 40b to stop operation of the pump 40b. Other types of devices may also be employed to detect fluid levels in fluid trap 28. For example, weight detectors may be employed to detect a predetermined weight limit as the fluid trap fills with exudate or other liquid. Alternatively, optical sensors or detectors may also be employed.

For the purpose of protecting the site of a wound from impact or abrasion during treatment, a reduced pressure appliance employing a rigid or semi-rigid wound cover may be utilized over the site of the wound. As shown in FIG. 2, a reduced pressure

appliance 29a includes a CPR mask 58 that provides a rigid wound cover for enclosing an appropriately-sized wound 74. The mask 59 is impermeable to fluids or gases so that a fluid-tight or gas-tight enclosure is effected over the wound site. The mask 59 is sufficiently rigid to support itself away from the wound during the application of suction or reduced pressure so that the mask 59 does not collapse into the wound 74. The CPR mask 58 is of the type having an inflatable air cuff 59 around the base of the mask. The cuff 59 may be inflated via an external valve for sealing the mask 59 against the normal skin 72 around the periphery of the wound 74. The air cuff 59 also prevents the base of the mask from digging into the skin 72 during application of reduced pressure. An optional screen 50 for preventing overgrowth of the wound 74 may be positioned to overlie the wound 74. The screen 50 may be formed of a rigid or semi-rigid perforated polymer surgical mesh such as Prolene mesh. Alternatively, a section of honeycombed polyethylene sheet may be cut to a suitable size and shape to overlie the wound 74. The screen 50 is held against the surrounding normal skin 72 in position overlying wound 74 by the cuff 59 which overlaps at least a portion of the periphery of the screen 50. The CPR mask 58 also includes a suction port in the form of a hose connector 54 to which one end of a suction tube 52 is attached. The other end of tube 52 is connected with a vacuum system 30 of the type previously described to provide a source of suction or reduced pressure for the appliance 29a. Suction produced within the appliance 29a may be sufficient to seal the cuff 59 to the skin and to thereby seal the appliance 29a in position over the wound site. However, in order to ensure a gas-tight seal between the reduced

pressure appliance 29a and the surrounding skin 72, the mask 58 may also be secured to the treatment site with a fluid impermeable adhesive seal 68. The adhesive seal 68 may be formed of a flexible adhesive material such as an adhesive tape or an adhesive sheet that has been cut to surround and at least partially overlie the cuff 59. As shown in FIG. 2, the adhesive seal is secured to the base portion of the rigid mask 58 and to the normal skin 72 around the periphery of the air cuff 59 to seal the mask in position over the wound site.

As shown in FIG. 3, a reduced pressure appliance 29b is depicted having a rigid, fluid impermeable, cup-shaped wound cover 88 overlying a wound site. The appliance 29b is used to treat a wound 114 without any screen either in the wound or overlying the wound. The cover cup 88 can be formed of a polymer such as polystyrene, HDPE, or other suitably rigid material. The cup 88 must be sufficiently rigid to support itself out of contact with the wound 114 during the application of suction or negative pressure so that the cup 88 does not collapse into the wound. Reduced pressure is supplied to the interior of the cup 88 through the suction tubing 82 connected to suction port 84 in the form of a nipple sealed in position on the cup 88. The tubing 82 is also connected with a suitable vacuum system 30 of the type previously described to provide a source of suction or negative pressure within the appliance 29b. The base of the cup 88 supports an inflatable air cuff 89 to seal the cup 88 to the skin and to prevent the cup 88 from digging into the skin 92 and causing discomfort when reduced pressure is applied. The cuff 89 is positioned upon the normal skin 92 surrounding the wound 94. While the suction created within the cup 88

may be sufficient to hold the appliance in position by causing the air cuff to seal to the skin, more effective attachment of the appliance to the surrounding skin 92 may be obtained by the use of a strip of fluid impermeable, adhesive material secured to the skin 102 and to the base of the cup 88 over the air cuff 89 around the periphery of the base of the cup 88. The layer of adhesive material 98 helps to ensure that a fluid-tight or gas-tight seal is maintained between the cup 88 and the surrounding skin 92 so that a fluid-tight enclosure is formed over the wound site.

Referring to FIG. 4, a reduced pressure appliance 29c is depicted for enclosing a wound site for the treatment of wound 114 with suction or reduced pressure. The reduced pressure appliance 29c includes a fluid-impermeable wound covering, generally designated 116, having an outer flexible, adhesive polymer sheet 117 applied over an inner, generally circular, semi-rigid shield 118, such as a polystyrene shield, for covering and enclosing the wound site. The base of the shield 118 is positioned over a circular pad 109 which may be formed from flexible tubing to prevent the base of the cup from digging into the skin 102 and causing discomfort when suction is applied to the appliance 29c. The pad 109 may also facilitate sealing of the cover shield 118 in position over the wound site to form a fluid-tight or gas-tight enclosure over the wound site. The pad 109 may be positioned directly onto the normal skin 102 surrounding the wound 114 or, as shown in FIG. 4, the pad 109 may overlie an outer peripheral portion of a rigid screen 100 in order to hold the screen 100 in a position overlying the wound to prevent wound overgrowth. A suction port 104 is provided at the top

of the shield 118 to permit gas-tight connection to suction tube 112. The suction port 104 may be in the form of a removable connector that is screwed into position at the top of the shield 118. Suction tube 112 functions to connect the appliance 29c to a suitable vacuum system 30 of the type previously described. For the purpose of enhancing the sealing of the appliance 29c in position over the wound site, an over-sized, generally circular, adhesive, fluid impermeable polymer sheet 117 is adhered and secured to the top surface of the shield 118. The oversized adhesive sheet 117 extends beyond the outer periphery of the shield 118 so that the adhesive sheet 117 provides a sealing ring 119 of material around the periphery of the shield. The sealing ring 119 is sealed and adhered to the normal skin 102 around the outer periphery of pad 109. When sealed in position overlying wound 114, the appliance 29c provides a generally fluid-tight or gas-tight enclosure over the wound site.

Referring to FIG. 5, a reduced pressure appliance 29d is depicted for enclosing and treating a wound 124 with suction or reduced pressure. A rigid or semirigid porous cup 138 is placed rim side down upon a porous screen or pad 120 located within a wound 124. The cup 138 has perforations 133 for equalizing pressure inside and outside of the cup 138. A flexible, fluid impermeable adhesive polymer cover sheet 128 is draped over the cup 138 to enclose the wound 124. The adhesive cover sheet 128 is adhered and sealed to the top portion of the cup 138 and to the surrounding normal skin 122 by adhesive layer 129 on the underside of the cover sheet 128 to provide a fluid-tight enclosure beneath the sheet 128. The cup 138 provides a generally central support beneath the

cover sheet 128 to hold the cover sheet 128 out of contact with the wound 124 during application of suction. The cup 138 has a central suction port 134 sealed in position at the top of the cup 128 to permit connection by suction tube 132 to a vacuum system 30 of the type previously described. When reduced pressure is supplied to the appliance 29d, the cover sheet 128 is deformed downward and inward to position 128a as shown in phantom in FIG. 5. Tension developed within the deformed sheet 128a by virtue of the suction is exerted upon the surrounding skin by the sheet at position 128a. The outer periphery 124a of the wound 124 is pulled inward by virtue of such tension to the position shown in phantom at 124b to promote closure of the wound. The tension within the sheet at position 128a also exerts a downward force upon the cup 138 which more firmly presses the cup 138 onto the wound 124. Such downward force on the cup 138 may be desired in such applications as flap or graft attachment to promote contact between the flap or graft and the underlying tissue. The pad 124 under the cup 138 helps to alleviate discomfort caused by the downward force on the cup 138.

For applications where a downward pressure of the appliance into a wound is not desired, a reduced pressure appliance 29e, as shown in FIG. 6, may be utilized having a support structure, generally designated 151, which is positioned external to a flexible sealing sheet 148 for covering a wound 144. The flexible cover sheet 148 is in the form of a flexible, fluid impermeable, adhesive polymer sheet. The reduced pressure appliance 29e shown in FIG. 6 includes an external support frame 151 in the form of a series of spider-like legs 158 radiating outwardly from a central support hub 155. The legs 158 hold the

central hub 159 directly over the wound 144. A connector 153 is removably mounted to the hub 155 to permit a suction tube 152 to be connected with the flexible cover sheet 148. The connector 153 may screw together and apart to permit the connector to be removably mounted relative to the hub 155. The flexible adhesive sheet 148 is adhered to the connector 153 at hub 155 and to the surrounding normal skin 142 so that the sheet is suspended over the wound 144 from the hub 155 in tentlike fashion. The flexible sheet is adhesively sealed to the connector 153 at the hub 155 and is also adhesively sealed to the skin 142 around the periphery of the wound 144 to form a fluid-tight or gas-tight enclosure over the wound site. The legs 158 of the frame 153 extend radially outward from the hub 153 and stand upon feet members 159 which may rest upon the outer periphery of the sheet 148 to help hold the cover sheet 148 in a position from being sucked together during the application of suction. Alternatively, the feet members 159 may extend beyond the cover sheet 148 and may rest upon the surrounding tissue beyond the periphery of the cover sheet 148. The connector 153 supported on the hub 155 provides a suction port 154 through which suction is supplied to the appliance 29e via suction tube 152. Tube 152 is connected to a vacuum system 30 of the type previously described for supplying reduced pressure within the cover sheet 148. When suction or reduced pressure is introduced via port 154, the sheet 148 deforms inwardly and downwardly to the position shown in phantom at 148a thus developing tension which is exerted upon the surrounding skin 142. The deformed sheet in position at 148a pulls the edges of the wound 144 inwardly to the position indicated in phantom at 144b hence

promoting closure of the wound 144.

Negative pressure appliances are useful for treating a variety of wounds. Treatment of a wound can be carried out by securing a negative pressure appliance to the treatment site as previously shown and described, and then maintaining a substantially continuous or cyclical reduced pressure within the appliance until the wound has reached a desired improved condition. A selected state of improved condition may include formation of granulation tissue sufficient for the attachment of a flap or graft, reduction of microbial infection in the wound, arrest or reversal of burn penetration, closure of the wound, integration of a flap or graft with the underlying wounded tissue, complete healing of the wound, or other stages of improvement or healing appropriate to a given type of wound or wound complex. It may be preferable to change the appliance periodically, such as at 48 hour intervals, during treatment, particularly when using appliances incorporating a screen on or in the wound. The method is preferably practiced using a negative or reduced pressure ranging from 0.01 to 0.99 atmospheres, and more preferably practiced using a negative or reduced pressure ranging between 0.5 to 0.8 atmospheres. The time period for use of the method on a wound may preferably be at least 12 hours, but can be, for example, extended for one or more days. There is no upper limit beyond which use of the method is no longer beneficial; the method increases the rate of closure up to the time the wound actually closes. Satisfactory treatment of various types of wounds has been obtained via the use of reduced pressures equivalent to about 2 to 7 in. Hg below atmospheric pressure.

Supplying reduced pressure to the appliance in an intermittent or cyclic manner has also been demonstrated to be useful for treating wounds. Intermittent or cyclic supply of reduced pressure to an appliance may be achieved by manual or automatic control of the vacuum system. A cycle ratio, the ratio of "on" time to "off" time, in such an intermittent reduced pressure treatment may be as low as 1:10 or as high as 10:1. The preferred ratio is approximately 1:1 which is usually accomplished in alternating 5 minute intervals of reduced pressure supply and non-supply.

A suitable vacuum system includes any suction pump capable of providing at least 0.1 pounds of suction to the wound, and preferably up to three pounds suction, and most preferably up to fourteen (14) pounds suction. The pump can be any ordinary suction pump suitable for medical purposes that is capable of providing the necessary suction. The dimension of the tubing interconnecting the pump and the reduced pressure appliance is controlled by the pump's ability to provide the suction level needed for operation. A 1/4 inch diameter tube may be suitable.

The present invention also includes a method of treating damaged tissue which comprises the steps of applying negative pressure to a wound for a selected time and at a selected magnitude sufficient to reduce bacterial density in the wound. Open wounds are almost always contaminated with harmful bacteria. Generally a bacterial density of $10^5$ bacterial organisms per gram of tissue is regarded as infected. It is generally accepted that at this level of infection, grafted tissue will not adhere to a wound. These bacteria must be killed, either through the wound host's natural immune response or through some

external method, before a wound will close. The application of negative pressure to a wound appears to reduce the bacterial density of the wound. It is believed that this effect is due to either the bacteria's incompatibility with a negative pressure environment or the increased blood flow to the wound area, as blood brings with it cells and enzymes to destroy the bacteria. The method can be used to reduce bacterial density in a wound by at least half. More preferably, it can be used to reduce bacterial density by at least 1,000 fold. Most preferably, the method can be used to reduce bacterial density by at least 1,000,000 fold.

The present invention also includes a method of treating a burn which comprises the steps of applying negative pressure to the burn over an area with predetermined reduced pressure and for a time sufficient to inhibit formation of a full thickness burn. A partial thickness burn, one which has a surface layer of dead tissue and an underlying zone of stasis, is often sufficiently infected so that it will transform within 24-48 hours into a full thickness burn, one in which all epidermal structures are destroyed. The application of negative pressure to the wound prevents the infection from becoming sufficiently severe to cause destruction of the underlying epidermal structures. The magnitude, pattern, and duration of pressure application can vary with the individual wound.

The present invention also provides a method for enhancing the attachment of living tissue to a wound which comprises the steps of first joining the living tissue to the wound to form a wound-tissue complex, then applying a negative or reduced pressure of selected magnitude to the wound-tissue complex over an

area sufficient to promote migration of epithelia and subcutaneous tissue toward the complex, with the negative pressure being maintained for a selected time period sufficient to facilitate closure of the wound. Attachment of living tissue to a wound is a common procedure that can take many forms. For example, one common technique is the use of a "flap," a technique in which skin tissue from an area adjacent to the wound is detached on three sides but remains attached on the fourth, then is moved onto the wound. Another frequently used technique is an open skin graft in which skin is fully detached from another skin surface and grafted onto the wound. The application of negative pressure to the wound-graft complex reduces bacterial density in the complex and improves blood flow to the wound, thereby improving the attachment of the grafted tissue. Further features of the apparatus and methods for the use thereof shall be made apparent in the following examples.

**Example 1 - Treatment of Open Wounds**

In order to demonstrate the use of a negative pressure appliance in the treatment of open wounds, an animal study was conducted using pigs as subjects. Pigs are frequently used as subjects in wound healing studies since they have essentially the same skin and subcutaneous tissue structure as humans.

Five 15 kg Chester pigs were obtained and acclimated for 1 week prior to use. The animals were sedated with an intramuscular injection of ketamine (25 mg/kg): xylazine (2.5 mg/kg): acepromazine (5 mg/kg). The backs and sides of the animals were shaved and scrubbed for surgery. One percent halothane was administered by endotracheal tube for maintenance of anesthesia. Two circular wounds were

created on the midline of the animals. The wounds were 2.5 cm in diameter having a depth reaching, but not including, the deep fascia over the spine (approximately 1 cm). Wounds in pigs in this site do not contract during healing. Alginate impressions were made of each wound to determine the volumes of the wounds.

A reduced pressure appliance of the type discussed in connection with FIGS. 2 and 11 was positioned over each wound, and the cups were sealed to the skin with an Ioban sheet. A non-compressible silicone tube was attached to the anterior appliance of each pig and a reduced pressure of 5 in. Hg below atmospheric pressure was supplied to the anterior appliances. No reduced pressure was applied to the posterior wounds. The animals were allowed to recover from anesthesia and given food and water *ad libitum*. The tubes were suspended from a pulley system over the top of each pen arranged to provide each animal with full, unrestricted access to its pen.

The animals were sedated 48 hours after surgery as described above, and then daily thereafter, so that alginate impressions could be made of each wound. This routine was continued until the wounded areas were filled with granulation tissue until coplanar with the surrounding tissue. The results of this experiment, including time to complete filling of the wound space by granulation tissue and the rate of granulation tissue formation, are presented in Table 1. The data in the third column of Table 1 shows the number of days needed for the treated and non-treated wounds to heal. In order to allow comparisons between the healing rate of variously-sized wounds, the data in the fourth column is expressed as a healing rate in terms of cc granulation tissue per day. As can be

seen, the treated wounds exhibited higher rates of healing than did the non-treated wounds. The wounds treated with reduced pressure filled with granulation tissue at an average rate that was 52.3% greater than the rate of granulation of the control wounds. Animals numbered 1 and 2 experienced intermittent loss of reduced pressure throughout the experiment, yet the treated wounds of these animals also healed significantly faster than their control wounds.

TABLE 1

| Animal | Wound | Initial Wound Volume ($cm^3$) | Days to Full Granulation | Fill Rate ($cm^3$/day) | % Rate Increase Due to Treatment |
|---|---|---|---|---|---|
| #1 | Control | 4.9 | 13 | 0.38 | |
| | Treated | 5.3 | 11 | 0.48 | 26.3 |
| #2 | Control | 7.2 | 8 | 0.90 | |
| | Treated | 9.3 | 8 | 1.16 | 28.9 |
| #3 | Control | 4.0 | 12 | 0.33 | |
| | Treated | 3.5 | 6 | 0.58 | 75.8 |
| #4 | Control | 4.7 | 11 | 0.43 | |
| | Treated | 5.0 | 7 | 0.71 | 65.1 |
| #5 | Control | 4.7 | 11 | 0.43 | |
| | Treated | 5.1 | 7 | 0.71 | 65.1 |
| Average | --- | --- | --- | --- | 52.3 |

**Example 2 - Reduction of Infection**

During the course of the experiment described as Example 1 above, it was observed that the reduced pressure-treated wounds were much cleaner and bled more spontaneously than non-treated wounds. It was therefore undertaken to determine the relative rates of clearance of a known bacterial inoculum from treated and non-treated wounds.

Five 15 kg pigs were obtained and wounds created as set forth in Example 1. Two 2.5 cm diameter defects were created on the dorsum of each pig using a sterile technique, with a 7.5 cm interval retained between the edges of the defects. Hemostasis was obtained by electrocautery. Prior to placement of the reduced pressure appliances, $10^8$ organisms of

Staphylococcus aureus in 1 ml saline solution were injected into each wound. The reduced pressure appliances of the type shown in FIGS. 2 and 11 were then attached as in Example 1, and a reduced pressure of 5 in. Hg below atmospheric pressure was applied to one of the wounds upon each animal. Reduced pressure was not applied to the other wound upon each animal. T-shirts were placed over the animals and no antibiotics were given during the course of the study. The animals were sedated as in Example 1 at 24 hour intervals, and a 3 mm diameter full thickness biopsy was taken from each wound site daily. The devices were then reattached and reduced pressure re-applied. This routine was continued for one week.

The biopsy samples were weighed and sterile saline (99X biopsy weight) added. The tissue samples were homogenized in a tissue grinder and serial dilutions were made in triplicate. 100 microliters of each dilution was plated on a blood agar plate and incubated overnight. The number of colonies were counted on each plate and thus the number of organisms per gram of tissue was calculated. The data was recorded as the common logarithm of the number of organisms/gram tissue and is shown in Table 2.

TABLE 2

Average $Log_{10}$(organisms/gm)

| | Day 0 | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 7 |
|---|---|---|---|---|---|---|---|
| Control | 8.44 | 8.04 | 8.17 | 7.13 | 7.13 | 8.82 | 7.08 |
| Treated | 7.69 | 7.36 | 7.37 | 6.79 | 6.43 | 3.98 | 4.32 |

As can be seen in Table 2, the common logarithm of the average number of organisms per gram of tissue present in the treated and non-treated wounds decreased slightly for all five animals over the first 4 days. In the treated wounds, the mean log of

organisms/gm decreased dramatically between days 4 and 5. The mean log of organisms/gm within the non-treated wounds increased during the same period. Using the traditional baseline of $10^5$ organisms/gm to define infection, the data of Table 2 shows that the average treated wound was disinfected after four days of treatment while the average non-treated wound was still infected after 7 days.

**Example 3 - Treatment of Burns**

Use of reduced pressure appliances upon burns has been found to retard the progression of partial thickness burns into full thickness burns. A partial thickness burn is a burn in which the depth of cell death due to thermal trauma does not extend below the level of the deepest epidermal structures (i.e., the base of hair follicles, sweat glands, sebaceous glands, etc.). A burn that is initially a partial thickness burn will often deepen and progress into a full thickness burn due to insufficient blood circulation to the epidermal cells beneath the partial burn.

**Example 3A**

The backs of five 15 kg pigs were shaved and scrubbed for surgery. A 1.5 inch diameter brass rod was heated to 190°C in an oil bath. The rod was pressed onto the pig's skin for 15 seconds following a well-known technique of relating depth of burn to time and temperature. Three burns were created over the spine of each pig, separated by 5 cm intervals. Suction apparatus cups of the configuration shown in FIGS. 2 and 11 were placed over two of the burns, with silver sulphadiazine (Silvadine) cream, the standard antibiotic cream applied to human burns prior to

excision of burned tissue, applied to the third. Cefaxolin (Kefzol) (500 mg) was administered intramuscularly (antibiotic). Suction (2-6 pounds vacuum) was applied to one of the cups. A small (2 mm) punch biopsy was taken of the wounded area and examined histologically for depth of burn.

Biopsies were analyzed by a dermatopathologist who was not told the nature of the study. It was concluded that the suctioned tissue specimens were healthier and healing more quickly than non-suctioned specimens.

**Example 3B**

A set of 2 cm diameter standardized depth partial thickness burns were created by pressing a heated metal rod to each side of five anesthetized pigs to create 16 burns on each side of each pig. Reduced pressure appliances of the type shown in FIGS. 2 and 11 were secured over each of the burns on the left side of each animal and a continuous pressure of 6 in. Hg was supplied to the reduced pressure appliances. The animals were anesthetized daily, and elliptical full-thickness biopsies extending from non-injured tissue, through the center of each burn, and into non-injured tissue were harvested, fixed in formalin, processed for histological analysis and stained with Hematoxylin/eosin and Gomori's trichrome. The histologic slides were then given to a Dermatopathologist for blind determination of burn depth according to the Breslow Local Scale of maximum depth of cell death below the surface of the skin.

The Breslow Level (maximum total depth) for the burns treated by reduced pressure was 0.095 mm. The maximum depth of the burns which were not treated by reduced pressure was 0.885 mm. The use of reduced

pressure appliances thus resulted in a 112% reduction in the maximum depth of burn progression.

**Example 3C - Treatment of Burn With Negative Pressure**

Patient B. is admitted with second and third degree burns over the face and upper extremities, including both hands, as a result of a house fire. A large mitten-shaped reduced pressure appliance of the general type shown in FIGS. 1 and 10 is placed over the patient's right hand, with open cell foam inserts placed between the fingers to apply reduced pressure to the interdigit spaces. Three pounds of vacuum is applied cyclically in a pattern of five minutes on, 5 minutes off. The appliance is changed on a three times per week schedule. Treatment is continued until the necrotic tissue sloughs off or is excised, followed by split thickness skin graft placement.

**Example 4 - Treatment of Flaps**

In order to determine the effect of reduced pressure application upon skin flap survival, five 15 kg Chester pigs were obtained and acclimated for 1 week as described previously. Two dorsally-based 3 cm by 12 cm flap outlines were drawn using indelible ink on each side of the pigs, leaving 6 cm between each flap. The flaps were assigned to one of four groups as follows:

(1) Dual-treated flaps are flaps that were exposed to reduced pressure both prior to and following surgery;

(2) Pre-treated flaps are flaps that were exposed to reduced pressure prior to surgery, but were not exposed to reduced pressure after surgery;

(3) Post-treated flaps are flaps that were exposed to reduced pressure following surgery; and

(4) Control flaps are flaps that were not exposed to reduced pressure either pre- or post-surgery.

The pre-treated flaps were initially treated by covering an area surrounding one of the flap outlines on the left side of each animal with a reduced pressure appliance of the type shown in FIGS. 1 and 10 having a large piece of open cell foam into which a tube was inserted. The foam was covered and sealed to the flap area with impermeable adherent sheeting. A reduced pressure of 7 pounds was then continuously applied to the area for 7 days.

On the day of surgery, each pig was sedated as previously described and anesthesia was maintained by 1% halothane. Two 3 cm by 12 cm dorsally based flaps were created on each side of the pig following the flap outlines. The flaps were created at a depth immediately below the *panniculus carnosus* (a subcutaneous muscle layer). The flaps were raised and then sutured back in place with single, interrupted sutures of 3-0 nylon. The reduced pressure appliances were then placed over the anterior flaps on each side of the animal. A reduced pressure of 5-7 pounds was continuously applied to the anterior flaps. Each suction tube ran from the appliances on the animals upward through a pulley suspended over the pens and down to a vacuum trap bottle to collect any liquid exudate. A hose was connected from each vacuum trap bottle to a vacuum pump to supply the reduced pressure to the appliances. The animals had free access to all areas of the pen.

The animals were anesthetized 72 hours after surgery and the appliances were removed. Photographs of each side of the animals were taken, and tracings of the flaps (and encompassing any discolored areas) were made on acetate to allow for planimetric

calculation of percent survival. The appliances were then replaced and reduced pressure re-applied. This routine was continued at 48 hour intervals until no further necrosis or healing of the flaps was observed.

The distal portions of all flaps were discolored 72 hours post surgery, with the flaps exposed to reduced pressure being lighter in color. The distal ends of all flaps appeared to necrose and an eschar formed over the distal portion of each flap. Over time the eschar spontaneously desquamated, exposing the outline of the original flap. The eschar over the control and pre-treated flaps consistently desquamated sooner than the post-treated and the dual-treated flaps. The control flaps had contracted to a Y shape which was evident after the eschar had desquamated. The dual-treated flaps had contracted slightly and appeared as long, thin rectangles after dislodgement of the eschar. The pre-treated flaps and post-treated flaps were intermediate between the control and dual-treated flaps in regard to flap contraction.

Dual-treated flaps exhibited the greatest survival in terms of percent retention (72.2%) of the original flap size. The post-treated flaps had the second greatest survival (67.4%). The pretreated flaps had the third most flap survival (64.8%). The control flaps had the least flap survival (51.2%). All treated flaps (dual-treated; pre-treated; and post-treated) exhibited significantly greater surface area survival than the control flaps. The dual-treated flaps had significantly greater surface area survival than either the pre-treated or post--treated flaps. The pre-treated flaps were not significantly different than post-treated flaps in regard to flap survival.

**Example 5 - Treatment of Decubitus Ulcers**

Application of reduced pressure was tested upon chronic decubitus ulcers and was found to be effective in the treatment thereof. Necrotic soft tissue was removed from the ulcers prior to placement upon the treatment site of a reduced pressure appliance of the type described in connection with FIGS. 1 and 10. Treatment of decubitus ulcers was tested using both continuous and cyclic application of reduced pressure. It was found that cyclic application of reduced pressure was both more effective and produced less discomfort for the patients than continuous application. Cyclic application of reduced pressure was conducted according to an application schedule of 5 minutes of suction followed by 5 minutes of non-suction. In 15 patients tested, successful treatment required from 2 to 13 weeks. Thirteen of the ulcers healed completely and every ulcer treated demonstrated progressive decrease in size during treatment. The following case histories demonstrate the manner in which various pressure sores were treated:

Case 1 - A 39 year-old male T4 paraplegic had suffered from multiple recurrent pressure sores over a period of 8 years. He had been treated for a trochanteric decubitus with a tensor fascia lata flap which had developed a recurrent ulcer in the center of the flap 4 months prior to presentation. The ulcer was debrided of necrotic tissue to non-involved periosteum resulting in a wound measuring 12 cm by 5 cm with a depth of 5 cm. During the course of 4 weeks of cyclic reduced pressure application, the wound progressively closed and spontaneously re-epithelialized. Reduced pressure of 5 in. Hg below atmospheric pressure was applied cyclically with 5 minute intervals of applied pressure followed by 5

minute intervals with no applied pressure. The wound remained healed more than 5 months after treatment.

Case 2 - A 45 year old male paraplegic suffered from a recurrent right ischial fossa pressure sore and abscess prior to treatment. Debridement of the wound was carried out with partial ischial resection. A week later, a re-advancement of the V-Y biceps femoris flap and rotation gluteus flap was performed. Six days later, the wound dehisced and the patient developed bilateral pneumonia requiring ventilatory support. The flap became progressively edematous and firm and resisted all efforts at mobilization. At this point, reduced pressure treatment providing continuous, non-cyclic suction or a vacuum at approximately five 5 in. Hg below atmospheric pressure was initiated. A total of 2 liters of fluid was removed by the reduced pressure appliance during the first 72 hours of treatment. Intravenous fluids were administered to replace the fluid removed from the wound. The appliance was replaced and the wound was examined three times each week. Treatment was continued for a total of six weeks during which the flap became progressively less indurated, granulation tissue formation rapidly progressed, the edges of the wound came into approximation, and the wound was healed completely.

Case 3 - A 51 year-old T1 paraplegic had multiple previous pressure sores culminating in bilateral asynchronous hip disarticulations and bilateral total thigh flaps. Seven months prior to admission, he developed a 7 cm by 23 cm pressure sore over the remnants of both ischia. Bone was exposed and no tissue was available for wound closure. Dressing changes over a period of three months had failed to improve the wound. A reduced pressure appliance was

then secured to the wound. During the first 3 weeks of treatment, reduced pressure of 5 in. Hg below atmospheric pressure was continuously applied. For the following 9 weeks, reduced pressure was applied cyclically in 5 minute intervals. The appliance was replaced every three days during treatment. In the course of the treatment, the wound first granulated to cover the bone completely and then the wound re-epithelialized from the margins. After 12 weeks of the treatment, a 2 cm by 5 cm scrotal flap was used to cover the midline area of the wound. The wound has remained stable beyond 6 months after treatment.

**Example 6 - Treatment of Dehisced Incisions**

A 50 year old debilitated white male who had undergone a colostomy through a midline laparotomy was re-admitted to the hospital for wound dehiscence and evisceration following an upper respiratory infection. He was taken immediately to the operating room and the abdominal wall was closed with Prolene mesh. Six weeks after placement of the Prolene mesh, the wound was still open and measured 28 cm by 23 cm. Only sparse granulation tissue had grown through the Prolene mesh during the six weeks. At this time a large reduced pressure appliance of the type shown in FIG. 5 was placed on an underlying porous aquaplast sheet (WFR/Aquaplast Corp., Wycoff, NJ 07481) over top of the Prolene mesh/wound surface and the space closed with a covering tent of Ioban. A continuous vacuum of 5 in. Hg below atmospheric pressure was applied. The appliance was changed three times per week. After 8 days of treatment, granulation tissue had grown through and totally covered the Prolene mesh. Two days later, the patient was taken to the operating room, where the surrounding tissue was

undermined and used to close 75% of the wound. Split thickness skin grafts were used to cover the remainder of the wound, and were placed on the bed of granulation tissue. There was 80% take of the grafts, and the remaining areas healed spontaneously with wet to dry dressing changes. The wound has remained stable 16 months after surgery.

**Example 7 - Treatment of Infected Wound**

Infected wounds have been successfully treated via application of reduced pressure as described in the following cases:

Case 1 - A 39 year old white male sustained severe avulsive trauma to his left lower extremity in a motor vehicle accident 10 years prior to presentation. He presented with a ten year history of chronic osteomyelitis and a 3 cm diameter open ulcer with exposure of bone of his left lateral malleolus. He had previously undergone 7 local surgical procedures to attempt closure of the wound. An arteriogram demonstrated a one vessel foot with diffuse atherosclerosis and post traumatic changes. The extremity was debrided of necrotic soft tissue and all involved bone saucerized. The patient was placed on a five week course of antibiotics. The day after debridement, a reduced pressure device of the type shown in FIGS. 2 and 11 was applied over the wound and a reduced pressure of 5 in. Hg below atmospheric pressure was applied. The device was changed on a three times per week schedule. After 14 days of treatment, the wound was smaller and filled with granulation tissue which completely covered the previously exposed bone. A split thickness skin graft was placed over the wound and healed primarily. The wound has been stable for 13 months with no recurrence

of osteomyelitis or tissue breakdown.

Case 2 - A 51 year old white male T8 paraplegic was admitted to the hospital for an infected left trochanteric pressure sore which had been present for one year and measured 4 cm by 6 cm. The patient had previously undergone multiple procedures for treatment of this condition including a V-Y advancement flap 4 months prior to presentation. A scan revealed possible chronic osteomyelitis of the left femur. It was decided to treat the potential osteomyelitis with a five week course of IV antibiotics. The wound was debrided, then treated using a reduced pressure appliance of the type shown in FIGS. 1 and 10 for 6 weeks with cyclical reduced pressure (5 in. Hg below atmospheric pressure; 5 minutes on/5 minutes off). The wound rapidly granulated and decreased in size. After 6 weeks the wound had closed and the patient discharged. The patient was readmitted 1 month later with a draining sinus tract to the bone. The previously scanned head of the left femur was resected and the wound closed primarily over drains. The wound healed without further problems.

**Example 8 - Chronic Open Wound Secondary to Stasis Ulcers**

A 45 year old black female patient with a 10 year history of bilateral stasis ulcers of the pretibial area was presented with bilateral 10 cm by 15 cm infected ulcers with exposed fascia. Two previous attempts at skin grafting in the previous year had failed. The patient was treated using a reduced pressure appliance of the type shown in FIGS. 1 and 10 for 14 days with cyclical (5 minutes on/5 minutes off) reduced pressure of approximately 5 in. Hg below atmospheric pressure. After 14 days treatment, quantitative bacterial counts of both ulcers were

below 102 bacteria/gram tissue, and both ulcers appeared as healthy granulating beds. Split thickness skin grafts were then applied and exhibited 100% take. The patient is ambulating, and the wounds have remained healed for 2 months, which is the longest the wounds had been healed in the last 10 years.

**Example 9 - Enhancement of Blood Flow**

It is believed that the efficacy of reduced pressure appliances in such treatments as have been described is due at least in part to enhancement of blood circulation within the treated wounds. In order to determine the effect of pressure application upon blood flow, a laser doppler needle probe was inserted into tissue adjacent to a pressure sore. A baseline flow level was recorded for thirty minutes. Then, the relative blood flow level was measured while a reduced pressure corresponding to 5 in. Hg below atmospheric pressure was continuously applied to the wound for 30 minutes using a reduced pressure appliance of the type shown in FIGS. 1 and 10. During continuous reduced pressure application, the relative blood flow level was only slightly higher than the baseline level.

Then the supply of reduced pressure to the appliance was cycled on and off at equal 5 minute intervals. During the "off" portions of the cycle, the relative blood flow level was twice as high as the baseline level. It is postulated that the increased blood flow during the off cycle is likely due to a "rebound" phenomenon. During the "on" cycle, blood is drawn toward the wounded tissue from both the venous and arterial branches of the vascular network in the vicinity of the wound. During the "off" cycle, this blood is transported toward the venous branch of the vascular network at a rate that is greater than would

have been observed in the absence of the preceding "on" cycle.

The terms and expressions which have been employed are used as terms of description and not of limitation and there is no intention in the use of such terms and expressions of excluding any equivalents of the features shown and described, or portions thereof, but it is recognized that various modifications are possible within the scope of the claimed invention.

What is claimed is:

1. An appliance for administering a reduced pressure treatment to a wound comprising:

(a) an impermeable cover for covering and enclosing the wound and for maintaining reduced pressure at the site of the wound;

(b) a seal for sealing said cover to tissue surrounding the wound; and

(c) reduced pressure supply means for connection to a source of suction for supplying said reduced pressure beneath the cover.

2. The appliance as recited in claim 1 comprising a screen for preventing overgrowth of wound tissue, said screen being locatable between said wound and said cover.

3. The appliance as recited in claim 2 wherein said screen comprises a porous sheet.

4. The appliance as recited in claim 1 wherein said reduced pressure supply means comprises a screen having an open cell foam and said reduced pressure supply means includes a segment of tubing embedded within said screen.

5. The appliance as recited in claim 1 wherein said cover is sufficiently rigid to protect the wound from impact and said reduced pressure supply means comprises a suction port on said cover.

6. The appliance as recited in claim 3 wherein said seal includes a cuff around the periphery of said cover for preventing said cover from digging into the skin during the treatment.

7. The appliance as recited in claim 1 wherein said seal includes an adhesive material on the cover for securing said cover to the tissue surrounding the wound.

8. An apparatus for treating a wound comprising:

(a) a vacuum system for producing a reduced pressure; and

(b) a reduced pressure appliance operably connected with said vacuum system for applying said reduced pressure to the wound, the appliance including:

(i) an impermeable cover for covering and enclosing the wound and for maintaining reduced pressure at the site of the wound;

(ii) a seal for sealing said cover to tissue surrounding the wound; and

(iii) reduced pressure supply means for connection with the vacuum system for supplying said reduced pressure to the wound.

9. The apparatus as recited in claim 3 wherein said vacuum system includes a collection device for collecting fluid aspirated from the wound.

10. The apparatus as recited in claim 3 wherein said collection device includes means for halting said application of reduced pressure to the wound when said fluid exceeds a predetermined quantity.

11. The apparatus as recited in claim 3 wherein said reduced pressure is from about 2 in. Hg below atmospheric pressure to about 7 in. Hg below atmospheric pressure.

12. A method of treating a wound comprising the steps of:

(a) applying a reduced pressure to the wound; and

(b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing.

13. The method as recited in claim 3 wherein said reduced pressure is from about 2 in. Hg below atmospheric pressure to about 7 in. Hg below atmospheric pressure.

14. The method as recited in claim 3 wherein said applying step comprises steps of:

(a) locating an impermeable cover over the wound, said cover having a suction port;

(b) sealing the periphery of said impermeable cover to tissue surrounding the wound; and

(c) operably connecting said suction port with a vacuum system for producing said reduced pressure.

15. The method as recited in claim 4 further comprising the step of placing a porous screen over the wound prior to said locating step.

16. A method of treating a wound comprising the steps of:

(a) securing an appliance for applying reduced pressure to the wound; and

(b) providing reduced pressure to said appliance in alternating intervals of application and non-application.

17. The method as recited in claim 6 wherein said reduced pressure is from about 2 in. Hg below atmospheric pressure to about 7 in . Hg below atmospheric pressure.

18. A method of pretreating a skin flap to promote attachment of the flap to a wound comprising the step of applying reduced pressure to a region of skin tissue adjacent to the wound prior to detachment of said skin tissue adjacent to the wound to form the flap from said region of skin.

19. The appliance of Claim 1 wherein said cover comprises a flexible sheet.

20. The appliance of Claim 19 comprising support means for supporting said sheet outward from the wound.

21. The appliance of Claim 20 wherein said support means comprises a support member located between said sheet and the wound.

22. The appliance of Claim 21 wherein said support member includes a porous cup member having attachment means for connecting with said reduced pressure supply means.

23. The appliance of Claim 21 further comprising a pad between the wound and said support member for alleviating discomfort caused in the wound by said support member.

24. The appliance of claim 20 wherein said support means comprises a support member extending

outwardly over the wound and external to said sheet.

25. The appliance of claim 24 wherein said support means comprises attachment means for attaching said sheet to said support means, said attachment means having a connecting member for connecting with said reduced pressure supply means for providing said reduced pressure beneath said sheet, and said support member comprising a plurality of leg members attached to said attachment means for holding said attachment means and said sheet outward from the wound.

26. The appliance of Claim 5 further comprising a screen adapted to prevent overgrowth of the wound for placement at a location between the wound and said cover and securable in said location by the periphery of said cover.

27. The appliance of Claim 26 wherein said screen comprises a sheet-like mesh.

28. The appliance of Claim 26 wherein said seal includes an adhesive material on the cover for adhering to tissue surrounding the wound and a seal member at least partially overlying said cover.

29. The apparatus of claim 8 wherein said reduced pressure supply means comprises a length of tubing connected between said vacuum system and said cover and wherein said vacuum system comprises:

(a) a vacuum pump connected with said tubing; and

(b) a filter for preventing said pump from venting micro-organisms aspirated from the wound.

30. The apparatus of Claim 29 wherein said filter is connected along said tubing between said pump and said cover for preventing contamination of said pump.

31. The apparatus of claim 8 wherein said vacuum system comprises control means for cyclically controlling said production of reduced pressure in alternating periods of production and non-production of reduced pressure.

32. The apparatus of Claim 10 wherein said reduced pressure supply means comprises a length of tubing, said collection device comprises an aspirating container connected along said length of tubing between said vacuum system and cover, and said halting means comprises a flotation valve within said aspirating container for blocking said tubing when a predetermined amount of fluid is collected within said container.

33. The apparatus of Claim 10 wherein said collection device comprises an expandable chamber and said means for halting said application of reduced pressure comprises sensing means for sensing expansion of said expandable chamber, said sensing means operatively connected with said vacuum system so that said reduced pressure is halted when a predetermined expansion of said expandable chamber is sensed by said sensing means.

34. The apparatus of claim 10 wherein said reduced pressure supply means comprises a length of tubing and said halting means comprises a filter along said tubing, said filter having pores that block the

supply of reduced pressure via said tubing when said pores are filled with said fluid.

35. The method of Claim 12 wherein said maintaining step is conducted in alternating periods of application and non-application of the negative pressure.

36. The method of claim 35 wherein each of said alternating periods is about 5 minutes.

37. The method of claim 12 wherein said selected stage of healing is cessation of partial thickness burn progression.

38. The method of claim 12 wherein said selected stage of healing is a reduction in bacterial density in the wound.

39. An assembly for supplying reduced pressure beneath an impermeable cover sealed to tissue surrounding a wound, the assembly comprising:

(a) an open cell foam screen for applying the reduced pressure to the wound; and

(b) a tube member embedded in said screen for extending from beneath the cover and for supplying the reduced pressure to said foam.

40. The assembly of Claim 39 wherein said tube member has a side port within the foam for promoting substantially uniform application of reduced pressure to the wound.

41. The assembly of Claim 39 wherein said foam screen is adapted to be conformed to the shape and

size of the wound.

42. A device for promoting closure of a wound comprising:

(a) an impermeable deformable cover for placement over the wound;

(b) an adhesive layer on the cover for forming a seal between said cover and tissue surrounding the wound;

(c) support means for supporting said cover outward from the wound forming an enclosed volume bounded by said cover and the wound and tissue surrounding the wound; and

(d) supply means for supplying reduced pressure to said enclosed volume and for deforming said cover so as to exert tension upon the tissue surrounding the wound.

43. The device of Claim 42 wherein said support means comprises a support member locatable within said enclosed volume.

44. The device of Claim 43 wherein said support member comprises a porous cup member.

45. The device of Claim 42 wherein said support means comprises a support member locatable external to said enclosed volume.

46. The appliance of claim 45 wherein said support means comprises attachment means for attaching said cover to said support means, and said support means comprises a plurality of leg members for supporting said cover out of contact with the wound.

47. A method of promoting attachment of a skin graft onto a wound comprising steps of:

(a) attaching the graft to the wound, and

(b) applying reduced pressure to the graft to promote blood circulation within the graft.

48. The method of claim 47 wherein the graft is a skin flap, the method further comprising steps of:

(a) applying reduced pressure to a region of skin adjacent to the wound, and

(b) forming the flap by detaching skin from said region prior to said attaching step.

49. The method of claim 47 comprising steps of:

(a) applying reduced pressure to a region of skin for use as the skin graft; and

(b) forming the graft by detaching skin from said region.

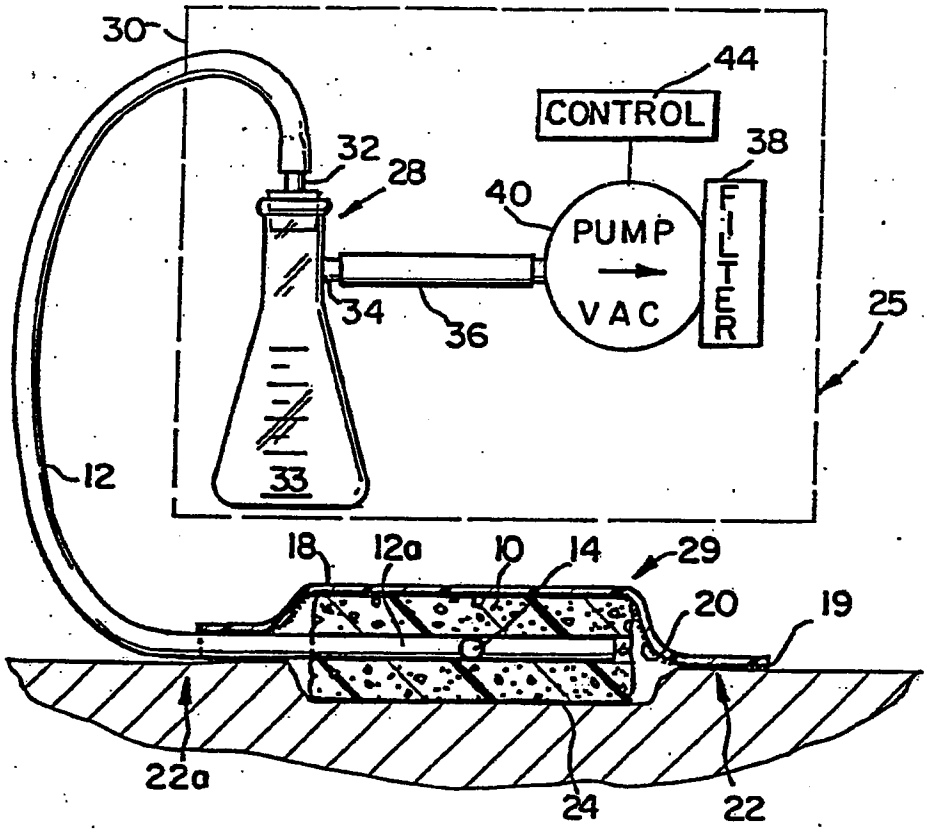


FIG. 1

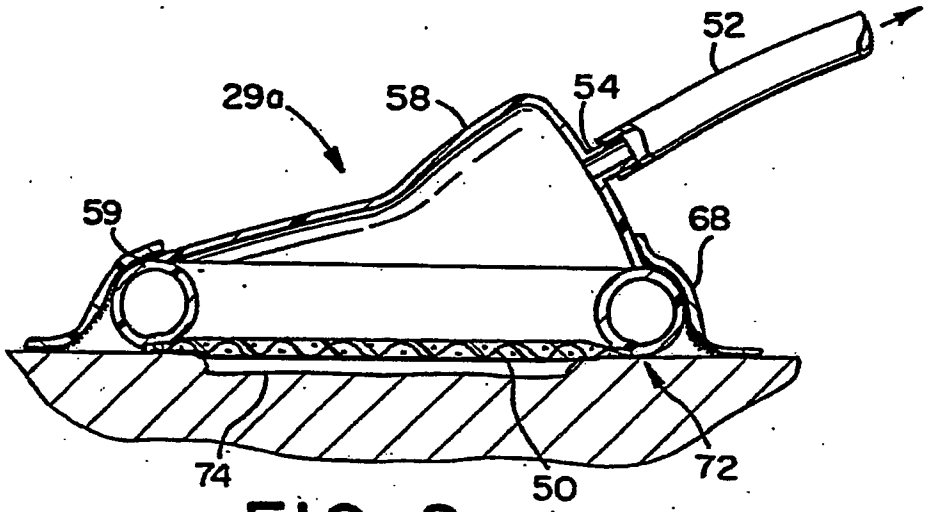


FIG. 2



SUBSTITUTE SHEET (RULE 26)

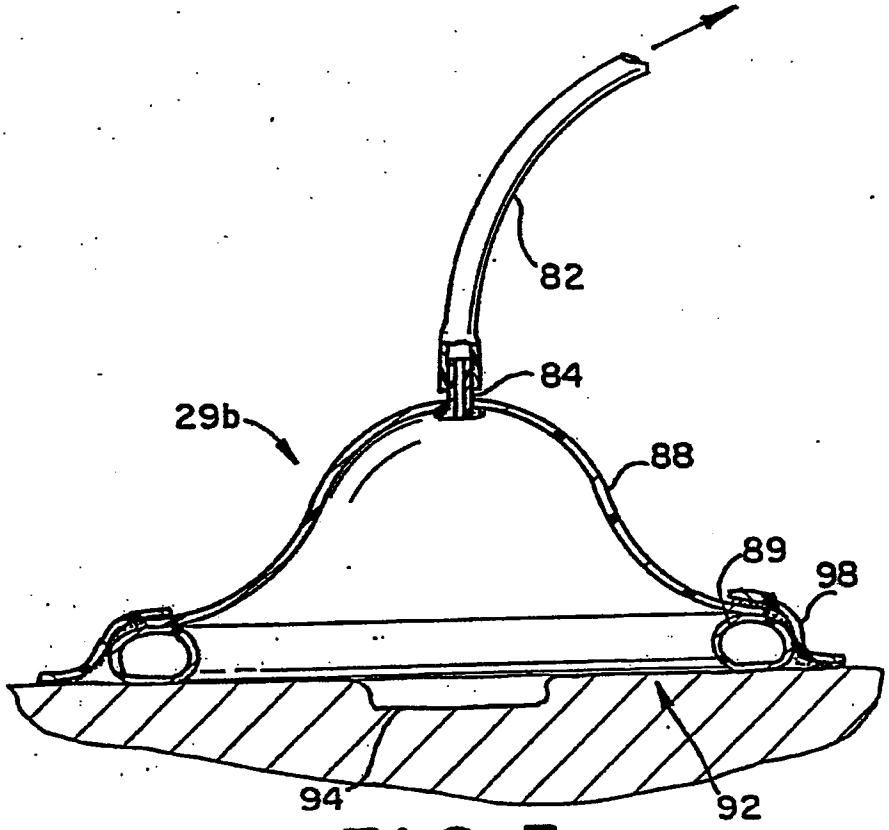
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FIG. 3

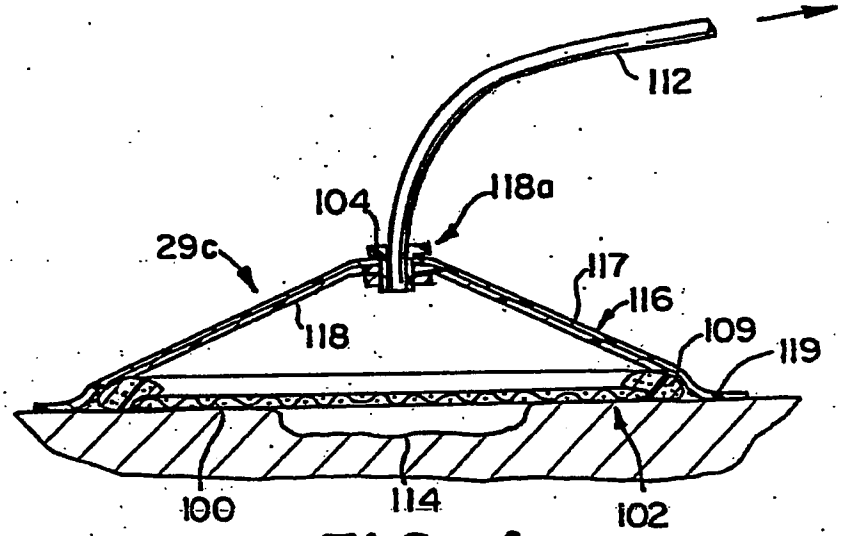
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FIG. 4

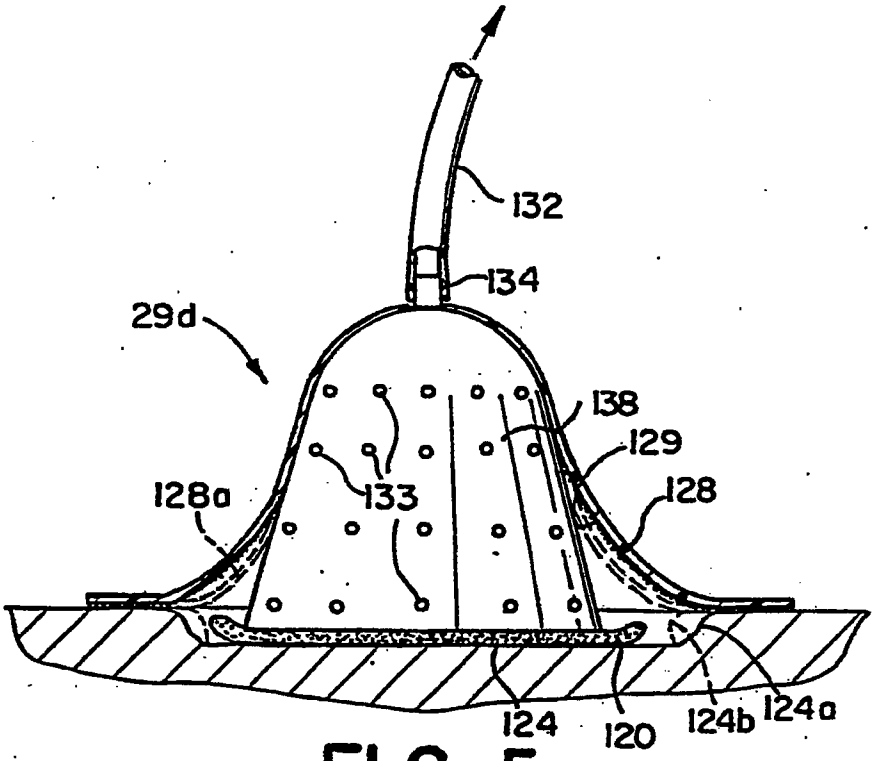
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FIG. 5

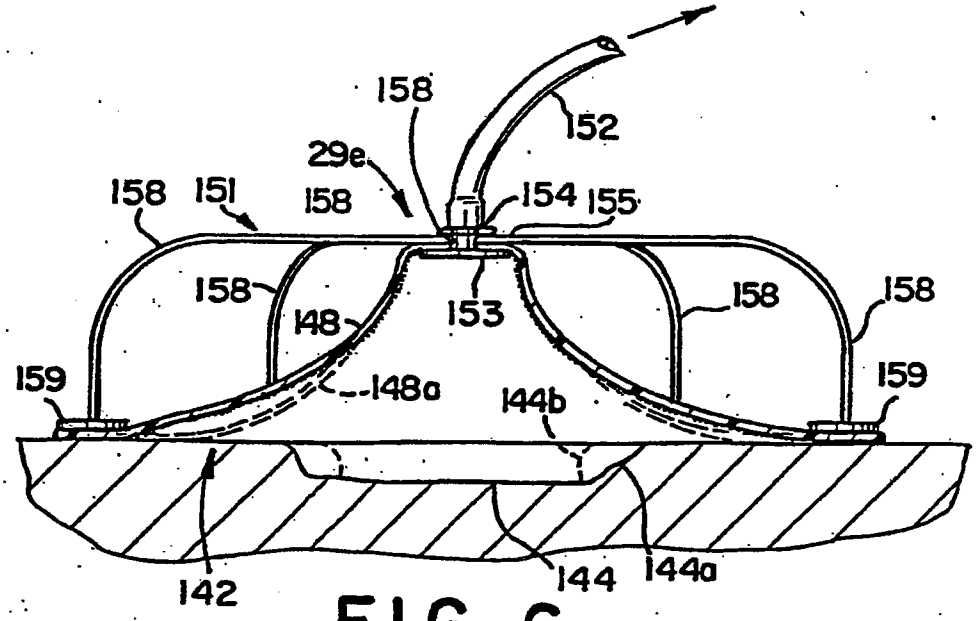
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FIG. 6

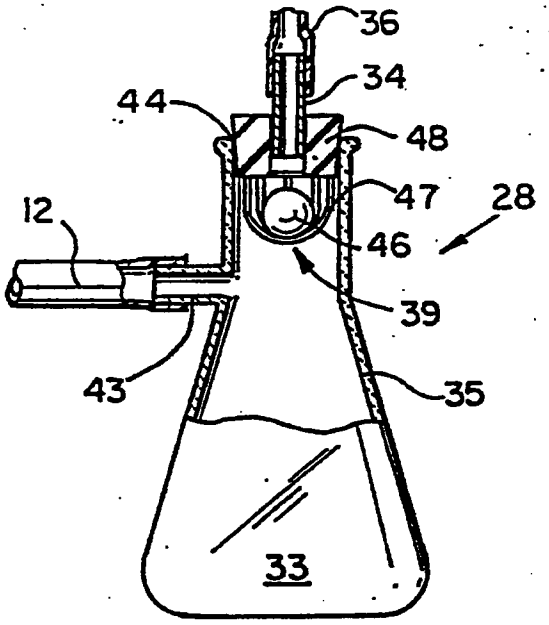


FIG. 7

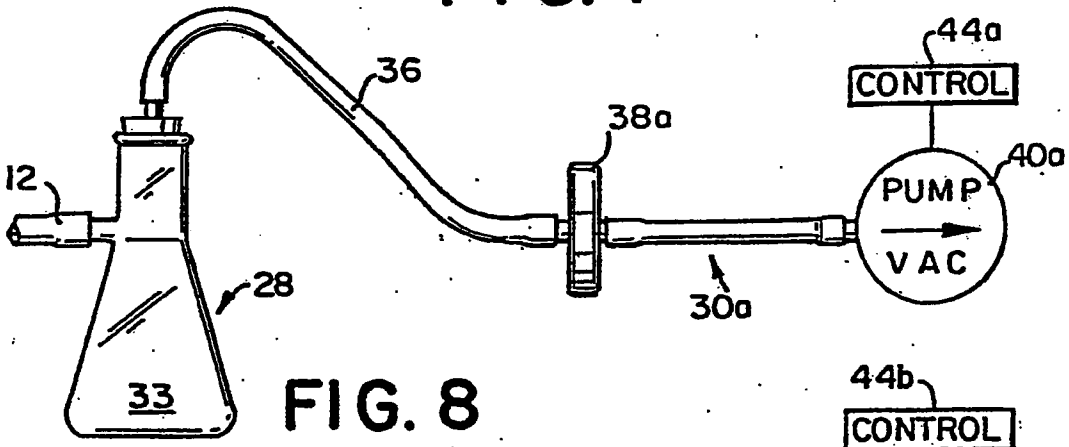


FIG. 8

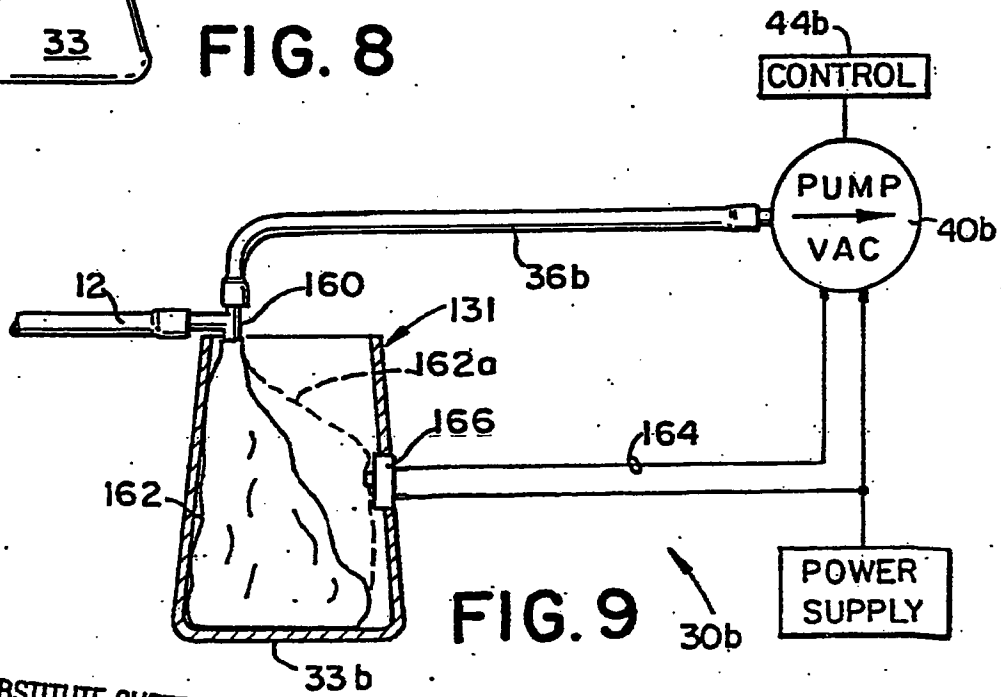


FIG. 9

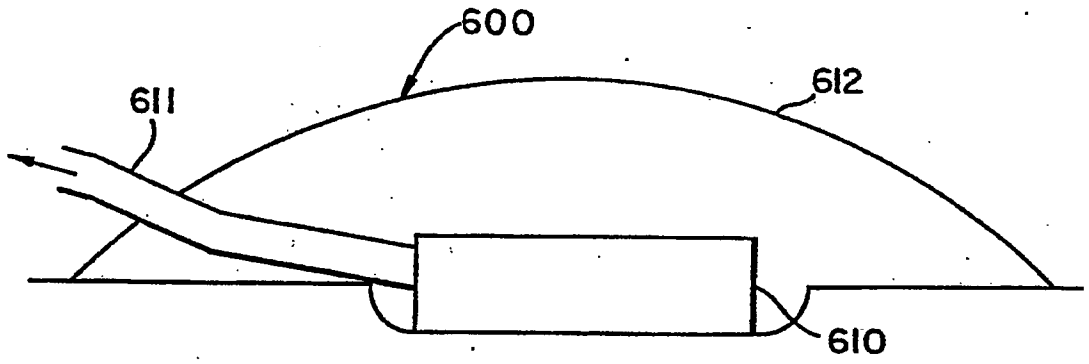


FIG. 10

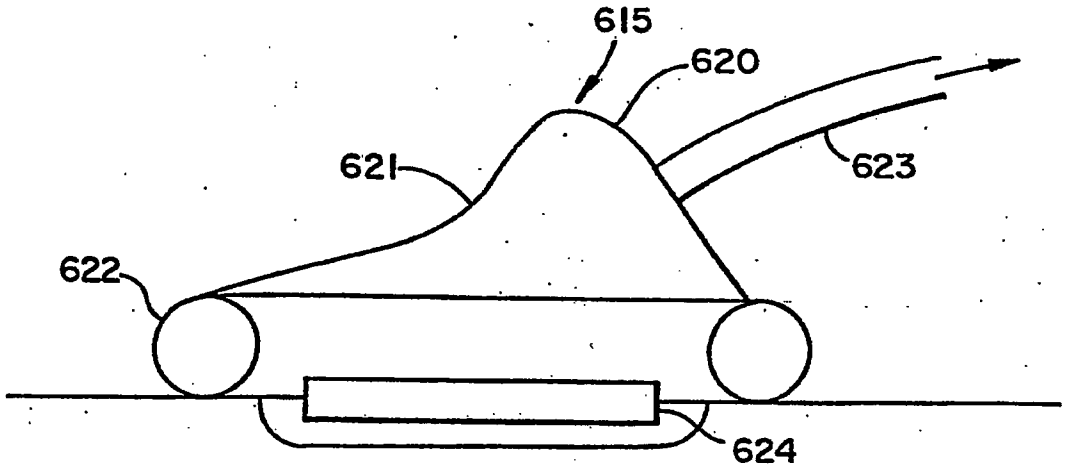


FIG. 11

INTERNATIONAL SEARCH REPORT

PCT/US94/02409

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 19/00

US CL :128/897

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/897-898; 602/42-53

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>---<br>Y | US, A, 3,874,387, (BARBIERI), 01 April 1975. See entire document. | 1, 5, 8-9, 12, 14<br>---<br>6-7, 11, 13 |
| Y | US, A, 4,834,110, (RICHARD), 30 May 1989. See entire document. | 6-7, 11, 13 |
| X | US, A, 4,382,441, (SVEDMAN), 10 May 1983. See entire document. | 39-41 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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| Date of the actual completion of the international search<br><br>18 APRIL 1994 | Date of mailing of the international search report<br><br>MAY 02 1994 |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. (703) 305-3590 | Authorized officer<br>FOR JOHN P. LACYK<br>Telephone No. (703) 308-0858 |

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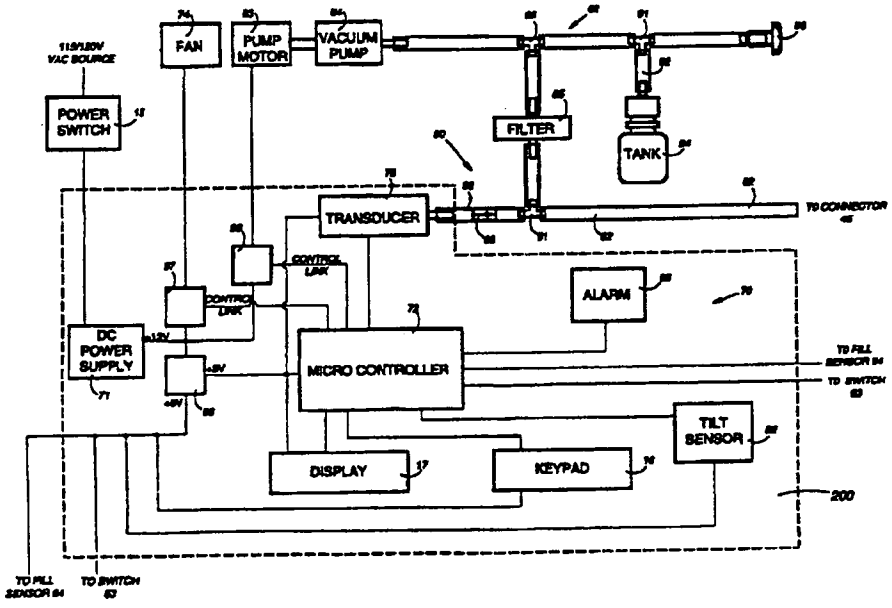
**Published**
*With international search report.*

(54) Title: WOUND DRAINAGE EQUIPMENT




(57) Abstract

A therapeutic apparatus is disclosed for stimulating healing of a wound in mammals. The apparatus comprises a porous foamed pad (36) connected by a tube (37, 38) to a canister (19). A vacuum pump is located within a housing having a recess (18) for receiving the canister. A bacterial filter (46) positioned over the outlet of the canister protects the vacuum pump from contamination by wound drainage fluids sucked into the canister.

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# WOUND DRAINAGE EQUIPMENT

The present invention relates to the healing of wounds and, more particularly, but not by way of limitation, to an apparatus for closing wounds that is compact, self-contained, and includes a disposable wound fluids canister.

Wound closure involves epithelial and subcutaneous tissue adjacent the wound migrating towards the centre of the wound until it closes. Unfortunately, closure is difficult with large wounds or wounds that have become infected. In such wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound. Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but are also less able to successfully fight bacterial infection and, thus are less able to close the wound naturally. Such wounds have presented difficulties to medical personnel for many years.

The most common technique for closing open wounds has been the use of sutures or staples. Although such mechanical closure techniques are widely practised and often effective, they suffer a major disadvantage by providing tension on the skin tissue adjacent the wound. That is, the tensile force required to achieve closure using sutures or staples causes very high localized stresses at the suture or staple insertion point. Such stresses commonly result in the rupture of the tissue at those points, which can eventually cause dehiscence in wounds, providing additional tissue loss.

Moreover, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalisation,

with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds, decubitus ulcers, ulcers resulting from chronic osteomyelitis, and partial thickness burns that subsequently develop into full thickness burns.

The above problem is discussed in WO 93/09727 which proposes as a solution a procedure for draining the wound by applying a continuous negative pressure to the wound over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound. Although WO 93/09727 deals in some detail with the clinical considerations of this kind of treatment, the apparatus described has certain practical shortcomings.

One problem with the apparatus described in the above prior document is that no means are disclosed for avoiding spread of infection from one patient to another or re-infection of the patient being treated.

In accordance with the present invention, there is provided a therapeutic apparatus for stimulating healing of wounds, said apparatus including a housing that contains a vacuum pump and a chamber for holding a disposable wound drainage collection canister. The canister preferably resides within the chamber and connects at an outlet with the vacuum pump and at an inlet with a porous pad. The pad is placed over a wound and adhesively secured thereto to create a sealed environment at the wound. Thus, when the vacuum pump activates, it evacuates air from the canister and thence the wound environment, resulting in the application of negative pressure to the wound, which in turn tends to promote drainage of fluids flowing from the wound into the canister. After the canister is filled, it is removed from the chamber, disposed of, and replaced with another canister to continue therapy.

Although the vacuum pump is designed to be reusable because of its more costly components, the apparatus utilizes a removable and disposable canister adapted to prevent contamination of the vacuum pump or the remainder of the apparatus. If the vacuum pump or other parts of the housing or the tubing leading to the pump from the canister became contaminated, the wound closure apparatus would have to be completely disassembled, thoroughly cleaned and possibly discarded. Disassembly and cleaning of the wound closure apparatus is extremely time and labour intensive, while disposal of the wound closure apparatus is expensive. Consequently, a removable and disposable canister prevents either of the above undesirable circumstances from occurring.

It is, therefore, an object of the present invention to provide a wound closure apparatus that closes wounds without stressing the surrounding skin.

It is another object of the present invention to render technology like that disclosed in WO 93/09727 available in a convenient, compact and self-contained, efficient and economically feasible system. It is also an object to optimize the safety and effectiveness of such a device, particularly from an infection control standpoint.

It is a further object of the present invention to provide a wound closure apparatus that includes a removable and disposable wound fluids collection canister to protect the wound closure apparatus from contamination.

Still other objects, features and advantages of the present invention will become evident to those skilled in the art in light of the following.

Figure 1 is a perspective view depicting the vacuum pump unit of a wound closure apparatus constructed according to the teachings of the present invention.

Figure 2 is a right side plan view depicting the vacuum pump unit of Figure 1.

Figure 2A is a detail view of the latch 26 portion of Figure 2, partially cut-away to eliminate guide (or "key") 29 from the view and to show portions of latch 26 in sagital cross section.

Figure 3 is a perspective view depicting a wound drainage collection canister for use in conjunction with the vacuum pump unit of Figure 1.

Figure 4 is a rear plan view depicting the wound drainage collection canister of Figure 3.

Figure 5 is a perspective view depicting the connection of a wound drainage collection canister of Figure 3 to a wound pad.

Figure 6 is a front plan view in partial cross section depicting the connection of the wound drainage collection canister of Figure 3 within the housing of the vacuum pump of Figure 1.

Figure 6A is a partial view of the apparatus shown in Figure 6 except the canister is removed.

Figure 7 is a perspective view depicting the filter carrier of the wound drainage collection canister.

Figure 8 is a top plan view depicting the filter cap of the wound drainage collection canister.

Figure 9 is a schematic view depicting the control system for a wound closure apparatus constructed according to the teachings of the present invention, and

Figure 10 is a section through a wound showing the wound pad in place.

As illustrated in Figures 1 and 2, front housing 11 and rear housing 12 connect together using any suitable means such as screws and fasteners to

provide wound closure vacuum pump 10 with a small, compact, and easily portable carrying case. Consequently, front housing 11 and rear housing 12 connect together to form handle 13 that permits easy carrying of wound closure apparatus 10. Except as maybe otherwise evident from this description, the carrying case of vacuum pump 10 is substantially as described and shown in WIPO Design No. DM/032185.

Front housing 11 includes power switch 15 that is movable between an on and off position to permit user control of the delivery of power to wound closure apparatus 10. Keypad 16 and liquid crystal display (LCD) 17 mount to front housing 11 to permit the programming of wound closure apparatus 10. Chamber 18 is defined by integrally formed interior side walls 100 and 101, top wall 102, bottom wall 103 and rear wall 104. Side wall 100 is dependently attached to the interior of front housing 11 by standard mounting hardware (not shown). The would fluids collection canister, illustrated in Figures 3-5, is received within chamber 18. Side walls 100 and 101 each include a key 29 and 30, respectively, the aid in the alignment of wound fluids collection canister 19 within chamber 18. Furthermore, front housing 11 includes latch 26 to secure the wound fluids collection canister within chamber 18.

Rear housing 12 includes arm 14 pivotally mounted to it within recess 110. An identical arm pivotally mounts to the opposite side of rear housing 12 within an identical recess. Arm 14 and its corresponding arm mounted on the opposite side of rear housing 12 pivot from within their recesses to a position where they support wound closure apparatus 10 at an angle. Arm 14 and its corresponding arm angularly support wound closure apparatus 10 to permit easier user access to keypad 16. Arm 14 and its corresponding arm may also be used to permit hanging of apparatus 10 from a hospital bed foot board.

Canister 19 has a shape as shown in Figures 3 to 6. As illustrated in Figures 3 to 6, canister 19 includes sidewalls 20 and 21, top wall 23, bottom wall 24, back wall 22 and front wall 25 that define the rectangular chamber for receiving blood, pus, and other fluids emitted from a wound. Sidewalls 20 and 21 include keyways 27 and 31 respectively, that receive a respective one of keys 29 and 30 to provide easy alignment of canister 19 within chamber 18. Furthermore, keyway 27 includes recess 28 that receives latch 26 to fasten canister 19 within chamber 18.

Front wall 25 of canister 19 includes raised portion 32 extending therefrom to furnish a window that permits a user to determine the level of wound fluids within canister 19. Accordingly, raised portion 32 is transparent so that the level of wound fluids within canister 19 may be visually determined. Raised portion 32 includes sidewalls 110 and 111, top wall 112, bottom wall 113, and front face 114 that define a chamber which opens into the chamber defined by sidewalls 20 and 21, top wall 23, bottom wall 24, back wall 22 and front wall 25 of canister 19. Front face 114 of raised portion 32 includes graduations that demarcate the volume of wound fluid within canister 19. Additionally, sidewalls 110 and 111 of raised portion 32 include ridges that provide a gripping surface for the user during the insertion and removal of canister 19 from chamber 18.

Although raised portion 32 is transparent to permit the determination of the level of wound fluids within canister 19, sidewalls 20 and 21, back wall 22, top wall 23, bottom wall 24, and front wall 25 are opaque or textured so that they are only translucent. As an alternative, the portions of canister 19 surrounding filter 46 may also be transparent. This enables a user to visually check for signs of contamination of filter 46. In this preferred embodiment,

sidewalls 20 and 21, back wall 22, top wall 23, bottom wall 24, front wall 25, and raised portion 32 of canister 19 are fabricated from a plastics material.

Canister 19 includes inlet 35 that is formed integrally with top wall 112 of raised portion 32. Inlet 35 is cylindrical in shape and communicates with the interior of canister 19 to permit the transfer of wound fluids into canister 19. In this preferred embodiment, inlet 35 is also fabricated from a plastics material.

In order to prevent liquids sucked into the canister from splashing directly onto cap 49, which masks the outlet 44, and to reduce foaming within the canister, inlet 35 has a blind inner end. Inlet 35 has a slot 35A so that drainage fluid is deflected downwardly into the raised handle portion 32 of the canister. Handle portion 32 may communicate with the main part of the canister through one or more holes in wall 25. It is desirable to avoid foaming because this can give a false reading when a capacitance sensing device is used to sense when the canister is filled. An anti-foaming material, e.g. a silicone may be added to the canister, e.g. by coating the interior walls. It may also be advantageous to include a gel-forming substance, e.g. a polyacrylamide or modified starch in order to immobilise the drainage fluid. This is particularly useful if the apparatus is likely to be tilted.

Wound fluids (i.e. drainage) are communicated through inlet 35 into canister 19 via pad 36 and hoses 37 and 38. In this preferred embodiment, pad 36 is fabricated from an open cell polyurethane or polyether foam. Hose 37 is inserted within pad 36 by making an incision in pad 36 and inserting the end of hose 37. Hose 37 can then be secured within pad 36 using any suitable means such as an adhesive or a flange. Preferably, the foam pad is moulded or formed with an elongated hole for the drainage tube which is an interference fit with the tube. The hoses are preferably made from medical grade PVC tube. Hose 38

mounts within inlet 35 using any suitable means such as an adhesive or welding. Hoses 37 and 38 include luer lock connectors 39 and 40, respectively, (or the equivalent such as any known quick disconnect type coupling) that attach together to permit communication between hoses 37 and 38. Furthermore, hoses 37 and 38 include pinch clamps 41 and 42, respectively, that are capable of sealing their respective hose 37 or 38 to prevent the flow of wound fluids. The foam pad is preferably packaged in a sterile container together with its connector and clamp. When packaged, the clamps will be in their open condition.

The communication of wound fluids into canister 19 requires the securing of pad 36 over a wound. Pad 36 is secured over a wound using cover 43 which is fabricated from a plastics material and includes an adhesive on one side that sticks to human skin. Wound cover 43 is conveniently a surgical drape material comprising a sheet of elastomeric material coated peripherally or overall with a pressure-sensitive adhesive, such as an acrylic adhesive. The elastomeric or rubbery nature of the wound cover is important because it accommodates changes in pressure in the wound area during intermittent operation of the vacuum pump. The wound cover is preferably a polyurethane film with a removable backing sheet, i.e. of polythene to protect the adhesive surface.

A high degree of reticulation in the polymer foam is desirable to achieve good permeability when the foam is under suction. Foams having at least 90% and especially at least 95% of interconnecting cells are preferred.

In use, the foam pad is cut to a size which corresponds closely to the edge of the wound with the objective of packing the foam into the wound cavity 210 so that it contacts the surface of the cavity, rather than bridging the cavity.

As depicted in Figure 10, the cavity may be extensive and there may be little or no tissue coverage to the bone 212. This is illustrated diagrammatically in Figure 10. Figure 10 is a cross-section through a wound showing the foam pad 36 packed into the wound cavity 210. It is important that the foam should be firmly packed into the recesses of the wound cavity. Drainage tube 37 terminates within the centre of the foam pad 36. Surgical drape 43 extends over the foam pad and is adhered to intact skin 211 around the periphery of the wound. Drape 43 is also firmly adhered around the tube 37 to prevent leakage of air. A wound cover is then adhered to the surrounding skin and around the drainage tube to provide an air-tight seal around the wound.

As illustrated in Figures 2, 4 and 6, canister 19 includes outlet 44 that mounts over port 45 to permit wound closure apparatus 10 to draw wound fluids into canister 19. Outlet 44 is cylindrically shaped and formed as an integral part of back wall 22 by outer wall 33 and inner wall 50 which are interconnected by end wall 34. Passageway 52, defined in part by interior wall 50 and in part by filter cap 49, provides the actual conduit for outlet 44 between the interior and exterior of canister 19. The placement of canister 19 within recess 18 such that outlet 44 resides over port 45 couples canister 19 to a vacuum pump. The vacuum pump removes air from canister 19 to create vacuum pressure within canister 19. That vacuum pressure is then transmitted to a wound site through hoses 37 and 38, thereby not only enabling therapeutic use of system 10, but also tending to promote wound drainage. Any wound drainage fluid is then drawn through pad 36 and hoses 37 and 38 into canister 19.

Outlet 44 resides near top wall 23 of canister 19 to ensure efficient operation of the vacuum pump. That is, the vacuum pump removes the most

air from canister 19 when the air does not have to first bubble through wound fluids contained in canister 19. Consequently, with outlet 44 positioned near the top of canister 19, the vacuum pump removes air directly from canister 19, and it is only during the final filling of canister 19 that air must bubble through wound fluids. Preferably, as described below, the apparatus includes detecting and warning means which operates before the level of the drainage fluid reaches either the inlet or outlet tube so that a fresh canister can be installed.

In removing fluids from a wound utilizing wound closure apparatus 10, a major safety concern is preventing wound fluids from contaminating the vacuum pump. Accordingly, filter 46 mounts over outlet 44 utilizing filter carrier 48 and filter cap 49 to block the flow of wound fluids to outlet 44 so that wound fluids remain within canister 19 and do not flow into the vacuum pump. In this preferred embodiment, filter 46 is a 0.2 micron hydrophobic membrane filter providing a bacterial barrier, although other filters may be substituted as appropriate.

As illustrated in Figure 7, filter carrier 48 includes face 53 formed integrally with lip 54. Face 53 includes groove 56 formed therein, while lip 54 supports brace 55 in its interior. Filter 46 fits within groove 56 of face 54 and is supported within filter carrier 48 by brace 55 of lip 54. An 'O' ring 53A is fitted in peripheral recess of filter carrier 48 to accommodate manufacturing tolerances and ensure a fluid tight seal in filter cap 49.

As illustrated in Figures 6 and 8, filter cap 49 includes cylindrical portions 57 and 58 which are formed integrally (with annulus 57' spanning therebetween), to hold filter carrier 48 within passageway 52 of outlet 44. To mount filter 46 over passageway 52, filter 46 is first placed within filter carrier 48 as described above. Filter carrier 48 is then positioned within filter cap 49

such that face 53 abuts annulus 57' of filter cap 49 and lip 54 of filter carrier 48 resides within annular lip 50' of outlet 44. Accordingly, when cylindrical portion 57 of filter cap 49 mounts over outlet 44, the front face 53 of filter carrier 48 and the outer edges of filter 46 abut annulus 57' to secure filter 46 within passageway 52. Filter cap 49 attaches to outlet 44 using any suitable means such as an adhesive or welding. Filter cap 49 is completely sealed except for aperture 51 positioned on top of filter cap 49. Aperture 51 communicates with port 45 via passageway 52 of outlet 44 to permit the vacuum pump to draw air from the interior of canister 19.

As illustrated in Figures 2 and 6, port 45 includes O-ring 59 mounted thereabout to provide a fluid tight seal between port 45 and inner wall 50 of outlet 44. Port 45 mounts through rear wall 104 of chamber 18 using any suitable means such as nuts 60 and 61. Furthermore, hose 62 attaches to the rear of port 45 using any suitable means such as a clamp to couple port 45 to the vacuum pump.

Switch 63 protrudes through rear wall 104 of chamber 18 to produce a signal indicating when canister 19 properly and securely resides within chamber 18. In this preferred embodiment, switch 63 is a normally open push button switch that mounts on rear wall 104 of chamber 18 using any suitable means such as a bracket. When canister 19 is properly positioned within chamber 18, its rear wall 22 presses the head of switch 63, closing switch 63 so that it provides a signal indicating that canister 19 properly resides within chamber 18.

Fill sensor 64 resides adjacent side wall 101, exterior to chamber 18. Fill sensor 64 provides a signal that indicates when canister 19 is filled with wound debris. In this preferred embodiment, fill sensor 64 is a capacitive sensor that mounts on side wall 101 of chamber 18 using any suitable means such as a

bracket or appropriate adhesive material. Fill sensor 64 has a sensing profile 64A which determines the point at which the capacitance measurement is made. When wound fluids have reached the level within canister 19 which corresponds to the location of the sensing profile 64A, the capacitance within canister 19 as 'seen' by fill sensor 64 changes, resulting in fill sensor 64 outputting a signal indicating that canister 19 is filled with wound fluids to the level at which the sensing profile is located. The position of this sensing profile behind wall 101 can be changed (see Figure 6A) to provide an optimum balance of space and volume utility.

As illustrated in Figure 2A, latch 26 generally comprises latch pin 65, handle 66 latch guide sleeve 68A and spring 67. Latch pin 65 comprises a proximal end 65A and distal end 65B. Latch guide sleeve 68A abuts the inner surface of front housing 11 and is held securely in place from the outer side of front housing 11 by nut 68B. Handle 66 screws onto the proximal end 65A of latch pin 65 and is locked in position by nut 69A. In the preferred embodiment, cover 68 over nuts 69A and 68B provides a surface against which handle 66 abuts, thus preventing end 65B from excessively entering chamber 18 as will be understood further herein. Cover 68 also provides aesthetic enclosure of nuts 69A and 68B. Dependent attachment of side wall 100 (chamber 18), as described hereinabove, is such that side wall 100 abuts latch guide sleeve 68A on the side distal front housing 11. Further, this arrangement causes distal end 65B of latch pin 65 to project into chamber 18 under the force of spring 67 (shown partially cut away). Spring 67 resides circumferentially about latch pin 65 within an axial bore of latch pin guide 68A. Spring 67 exerts force between distal end 65B of latch pin 65 and an annulus within the axial bore of latch pin guide 68A. A transverse slot in the distal end of latch pin guide 68A receives

end 65B of latch pin 65, providing rotational alignment of end 65B and further recess for end 65B when a user "pulls" handle 66 in an axial direction.

Latch 26 operates to ensure canister 19 remains secured within chamber 18. End 65B of latch 26 terminates in a point that protrudes through key 29 into chamber 18. During the placing of canister 19 within chamber 18, key way 27 of canister 19 forces the point 65B of the latch pin within key 29. However, once canister 19 has been properly positioned within chamber 18, recess 28 resides below latch pin end 65B so that spring 67 biases the point 65B of latch pin 65 into recess 28 to prevent the removal of canister 19 from chamber 18. The removal of canister 19 from chamber 18 is accomplished by grasping handle 66 and pulling the point 65B of latch pin 65 from recess 28. With the point of latch pin 65 no longer within recess 28, canister 19 may be pulled from chamber 18 using its raised portion 32.

As illustrated in Figure 9, wound closure apparatus 10 preferably plugs into a standard 115/120 VAC power source (e.g. an outlet) to supply power to control system 70. Alternative embodiments (not shown, although similar) are readily adapted for 220 VAC power by changing the power cord and appropriately re-wiring the tops of the transformer within the DC power supply 71 as is readily know in the art. The application of power to control system 70 is regulated by power switch 15 which is a standard push button on/off switch. With power switch 15 depressed, DC power supply 71 receives the 115/120 VAC signal and converts it into a 12 VDC signal for use by fan 74 and motor 83. A conventional voltage regulator 96 steps down the voltage to +5V or 12V for use by each of the other DC components 63, 16, 17, 82, 72 and 75. Voltage regulator 96 connects to keypad 16, LCD 17, switch 63, microcontroller 72, transducer 75, and tilt sensor 82 to supply each of them with the +5V DC

signal. Microcontroller 72 links to solid state relays (MOSFETs) 97 and 98 for controlling the provision of the 12 VDC power supply to fan 74, pump motor 83 and fill sensor 64, respectively.

As illustrated in Figure 1, once power switch 15 is depressed, a user employs keypad 16 and LCD 17 to select the operating parameters for wound closure apparatus 10. Wound closure apparatus 10 stores the previously selected operating parameters so that upon power initialization, LCD 17 displays the phrase "NEW PATIENT" with the word "NO" over arrow button 76, and the word "YES" over arrow button 77. If the user presses arrow button 76 to answer no, wound closure apparatus 10 will operate at the previously selected parameters. After answering no, the user presses on/off button 78 to begin operation of wound closure apparatus 10.

Conversely, if the user presses arrow button 77 to indicate a new patient, wound closure apparatus 10 will operate either under default values or allow the user to select the operating parameters. To operate under default parameters, the user presses on/off button 78 after pressing arrow button 77. However, to select his or her own values, the user presses option button 79 after pressing arrow button 77.

Upon the pressing of option buttons 79, LCD 17 displays a bar graph representing the spectrum of available vacuum pump pressures and a numerical representation of the vacuum pump pressure presently displayed by the bar graph. The user changes vacuum pump pressure using arrow buttons 76 and 77. The pressing of arrow button 76 reduces vacuum pump pressure, while the pressing of arrow button 77 increases vacuum pump pressure. After selecting the desired vacuum pump pressure, the user presses option button 79 to save the selected vacuum pump pressure.

Once the selected vacuum pump pressure has been saved, LCD 17 displays the pump operation times available to the user. The user may program wound closure apparatus 10 to pump either continuously or intermittently. Thus, LCD 17 displays the word "CONTINUOUS" over arrow button 76 and "INTERMITTENT" over arrow button 77. The user selects continuous operation by pressing arrow button 76 followed by on/off button 78 to activate the vacuum pump. In its continuous mode, wound closure apparatus 10 runs its vacuum pump continuously until on/off button 78 is pressed again.

If the user presses arrow button 77 to select intermittent operation, LCD 17 displays a bar graph or figures representing the minimum and maximum on times for the vacuum pump. LCD 17 also displays the phrase "ON TIME" and the numerical value presently displayed. A user decreases the on time of the vacuum pump by pressing arrow button 76 and increases the on time of the vacuum pump by pressing arrow button 77. After selecting the desired on time, the user presses options button 79 to save the selected on time value.

LCD 17 then displays a second bar graph or figures representing the off time for the vacuum pump with the phrase "OFF TIME" and the numerical value presently depicted by the bar graph. Again, arrow buttons 76 and 77 are pressed to increase or decrease, respectively, the off time for the vacuum pump. After selecting the off time, the user presses options button 79 followed by on/off button 78 to operate wound closure apparatus 10 using the selected parameters.

Keypad 16 includes setting button 80 to permit the user to sequentially display the currently selected operating parameters of wound closure apparatus 10. Keypad 16 further includes delay button 81 to permit the user to deactivate an alarm sounded in response to an improper operating condition of wound

closure apparatus 10. Delay button 81 provides the user with the ability to silence alarms so that the alarm will not have to be listened to during the correction of the problem.

Any new alarm conditions occurring within the fifteen minute period ("delay period") after the pressing of delay button 81 will not be indicated by an audible alarm. However, the pump will still be deactivated when appropriate, even during the delay period.

Again referring to Figure 9, microcontroller 72 is a multi-port microprocessor with a eight-bit analog to digital (A/D) converter having associated memory that stores the program directing microcontroller 72 during its control of wound closure apparatus 10. After receiving and storing the user selected operational parameters and receiving an on signal due to the pressing of on/off button 78, microcontroller 72 activates pump motor 83 which, in turn, drives vacuum pump 84 to begin the removal of air from canister 19.

As vacuum pump 84 operates, it draws air from within canister 19, into hose 62 via outlet 44 of canister 19 and port 45. Hose 62 connects to filter 85 and transducer 75 via T-junction 91. Filter 85 is similar to filter 46 and thus ensures no wound fluids contaminate vacuum pump 84. Filter 85 communicates with pump 84 via T-junction 88 and one arm of the latter is connected to bleed valve 86. Bleed valve 86 communicates with the atmosphere to release pressure developed within line 62 by vacuum pump 84 after microcontroller 72 deactivates vacuum pump 84. Bleed valve 86 is sufficiently small to ensure that it generally does not affect the vacuum pressure levels achieved by vacuum pump 84 as it evacuates air from canister 19, except to prevent over pressurisation beyond 250 mmHg and to prevent erratic operation of the vacuum pump at very low pressure settings..

In the preferred embodiment, an orifice of 0.5 mm diameter is especially preferred for bleed valve 86. Valve 86 or the equivalent is particularly important for enabling intermittent application of negative pressure, as the orifice allows for gradual release of the negative pressure (over a period of about fifteen seconds) when the pump motor 83 is de-actuated. Bleed valve 86 is positioned outside housing 11 to facilitate un-clogging of aperture 86 in the event of a blockage. An aperture is provided in bleed valve 86, which is machined from stainless steel. Flow control orifices would be alternatives.

Line 62 also includes T-connector 91 to connect it with line 92. Line 92 is connected to tank 94 which acts as a damper to pressure changes in line 62. This dampening effect, facilitated by restrictor 89 in line 93 between transducer 75 and T-junction 91, causes the pressure measured by transducer 75 to be an accurate indication of actual wound site pressure. Transducer 75 communicates with line 62 via line 93 to measure tank 94 pressure and produce an electrical signal representative of that pressure. Transducer 75 outputs its pressure signal to microcontroller 72.

Microcontroller 72 utilizes the pressure signal to control the speed of pump motor 83. As previously described, the user selects either a default vacuum pump pressure or a desired vacuum pump pressure for the operation of wound closure apparatus 10. After receiving the wound pressure signal from transducer 75, microcontroller 72 compares the wound pressure with the user selected pressure. If the wound pressure is higher than the user selected vacuum pump pressure, microcontroller 72 reduces pump motor speed to decrease vacuum pump pressure and thus the pressure at the wound. Conversely, if the wound pressure is less than the user selected vacuum pump

pressure, microcontroller 72 increases the speed of pump motor 83 resulting in an increase in the vacuum pressure applied at the wound.

Microcontroller 72 controls pump motor 83 by varying the amount of voltage received by pump motor 83. That is, microcontroller 72 receives the 12V DC signal from DC power supply 71 and outputs a voltage between 0 and 12V DC to pump motor 83 to control its speed in accordance with the user selected vacuum pump pressure value. Accordingly, microcontroller 72 employs feedback to ensure that the wound experiences the user selected vacuum pump pressure. If the target pressure is not reached after a period of five minutes, microcontroller 72 deactivates motor 83 and sounds the audible alarm. Additionally, the feedback signal prevents maximum vacuum pump pressure from being exceeded. If the wound pressure measured by transducer 75 exceeds a maximum safe vacuum pump pressure, microcontroller 72 deactivates pump motor 83.

Wound closure apparatus 10 includes fan 74 to cool pump motor 83 and printed circuit board or chassis 200 during the operation of the wound closure apparatus 10. In the preferred embodiment, microcontroller 72 controls fan 74 to always operate while power is being supplied. In alternative embodiments, however, microcontroller 72 controls fan 74 to operate only in relation to motor 83, because it is only necessary for fan 74 to operate if motor 83 is also operating. In such alternative, as long as pump motor 83 operates, microcontroller 72 runs fan 74. However, when microcontroller 72 deactivates pump motor 83 it also deactivates fan 74.

Control system 70 includes fill sensor 64 to provide a signal to microcontroller 72 that indicates when canister 19 is completely filled with wound fluids. After receiving a signal from fill sensor 64, microcontroller 72

deactivates pump motor 83 and fan 74 and activates alarm 95 to signal the user that canister 19 must be replaced.

Control system 70 includes switch 63 to prevent users from operating wound closure apparatus 10 without a canister properly installed. If a canister is not properly installed, switch 63 remains open and therefore outputs no signal to microcontroller 72. If microcontroller 72 receives no signal from switch 63, indicating no canister within chamber 18, it will not supply power to pump motor 83 even after a user has pressed on/off button 78. Furthermore, microcontroller 72 activates alarm 95 to signal the user that either a canister is not properly installed or is improperly installed within chamber 18 when therapy is activated. Microcontroller 72 operates pump motor 83 only if switch 63 is depressed to provide a signal indicating the proper placement of a canister within chamber 18.

Control system 70 includes tilt sensor 82 to prevent operation of wound closure apparatus 10 if it is tilted excessively. Excessive tilting of wound closure apparatus 10 during operation diminishes the efficiency of removal of wound fluids and, more importantly, might result in either the contamination of vacuum pump 84 or the spilling of wound fluids. Thus, if wound closure apparatus 10 tilts along any of its axes beyond a predetermined angle (approximately 45$^{o}$ in this preferred embodiment), tilt sensor 82 outputs a signal to microcontroller 72. In response, microcontroller 72 deactivates pump motor 83 and activates alarm 95 to signal the user of the excessive tilt situation. In this preferred embodiment, tilt sensor 82 may be implemented with any standard mercury switch. The tilt circuiting and alarm operates as follows. If therapy is in progress and the pump unit is tilted, the alarm will sound and the liquid crystal display 17 will state 'unit tilted'. Therapy is automatically stopped.

When the unit is returned to the vertical, therapy will be automatically reinstated after a time delay (e.g. about 30 seconds) has elapsed..

CLAIMS:-

1. A therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad which is permeable to fluids for introduction into the wound, a dressing for covering the wound and providing an air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound, to draw fluids therefrom, said tube being connected to the pump via a canister for collecting fluids sucked from the wound, and at least one filter being interposed between the canister and the pump.

2. Apparatus as claimed in claim 1 wherein said filter is located in the canister.

3. Apparatus as claimed in claim 1 or 2 wherein the canister is removably attached to a housing for the pump.

4. Apparatus as claimed in claim 3 wherein the canister is removably received in a recess in the housing.

5. Apparatus as claimed in any one of the preceding claims which includes means for detecting when said canister is substantially full with fluid.

6. Apparatus as claimed in claim 5 wherein said means comprises capacitance sensing means arranged to sense a change of capacitance as said canister fills with liquid.

7. Apparatus as claimed in any one of the preceding claims wherein said pad is a polymer foam having interconnecting cells.

8. Apparatus as claimed in claim 7 wherein the foam is a reticulated foam having at least 90% of interconnecting cells.

9. Apparatus as claimed in claim 8 wherein said foam has at least 95% of interconnecting cells.

10. Apparatus as claimed in claim 7, 8 or 9, wherein said drainage tube is fitted into the interior of the foam as an interference fit.

11. Apparatus as claimed in any one of claims 7 to 10 wherein said foam is a polyether foam.

12. Apparatus as claimed in any one of the preceding claims in which said dressing is an elastomeric film which is coated at least in the peripheral areas with a pressure-sensitive adhesive.

13. Apparatus as claimed in claim 12 wherein said film is a polyurethane film.

14. Apparatus as claimed in any one of the preceding claims which is adapted to apply continuous or intermittent suction to the wound.

15. Apparatus as claimed in claim 14 wherein a bleed device is provided between the canister and the pump to permit release of negative pressure during intermittent operation.

16. A sterile pack for use in conjunction with a vacuum pump and canister for stimulating wound healing by drainage, said pack comprising a polymer foam pad of reticulated open-celled foam having a drainage tube sealed within the foam.

17. A pack as claimed in claim 16 wherein said foam comprises more than about 95% interconnecting cells.

18. A pack as claimed in claim 16 or 17 which includes connector means for connecting the tube to said canister or to a tube attached to said canister.

19. A pack according to any one of the preceding claims wherein the tube is fitted into the foam by an interference fit.

20. A canister for use in the apparatus as claimed in any one of claims 1 to 15 which comprises a moulded plastics container having an inlet for connection to a wound dressing pad and an outlet for connection to a suction pump, said outlet incorporating a bacterial filter.

21. A canister as claimed in claim 20 which includes deflector means for deflecting liquid sucked through the inlet in a direction towards the bottom of the canister.

22. A canister as claimed in claim 20 or 21 which includes an anti-foaming substance.

23. A canister as claimed in any one of claims 20 to 22 which includes a gel-forming substance, which is capable of immobilising drainage fluids within the canister.

24. Therapeutic apparatus is claimed in any one of the preceding claims which includes a tilt sensor adapted to give an audible and/or visual alarm when the apparatus is tilted beyond a predetermined angle from vertical.

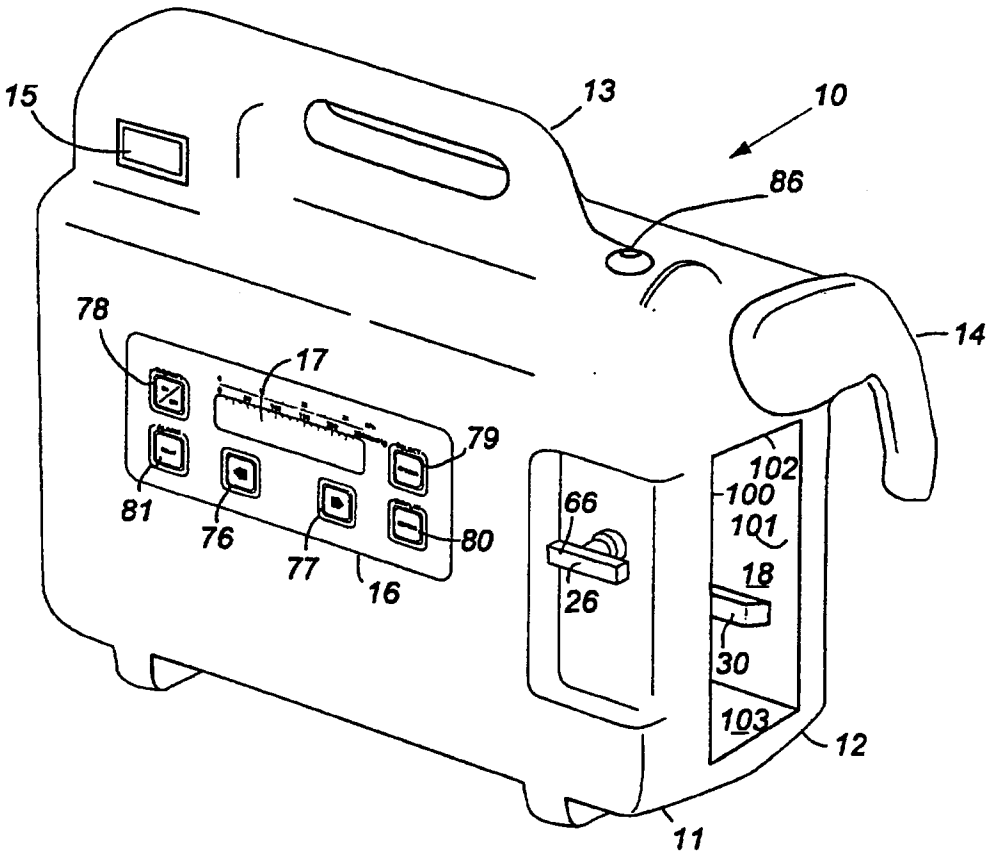
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FIG.1

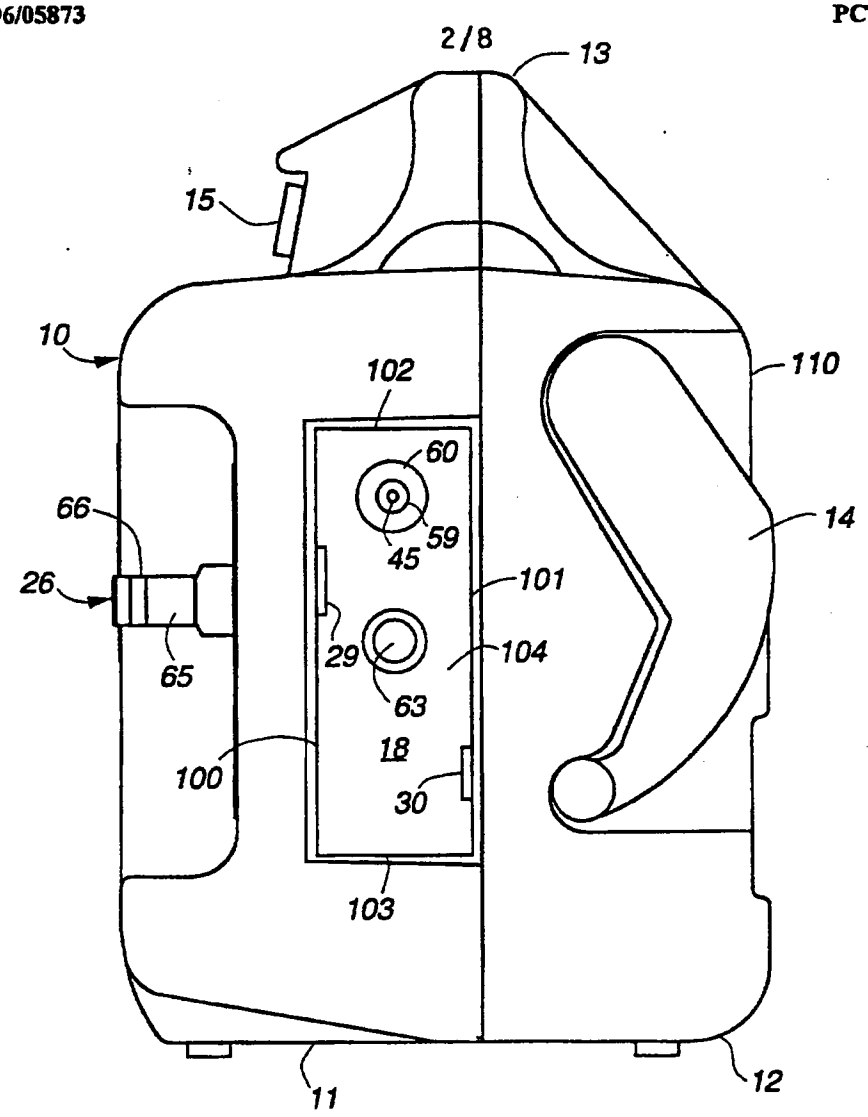
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FIG.2

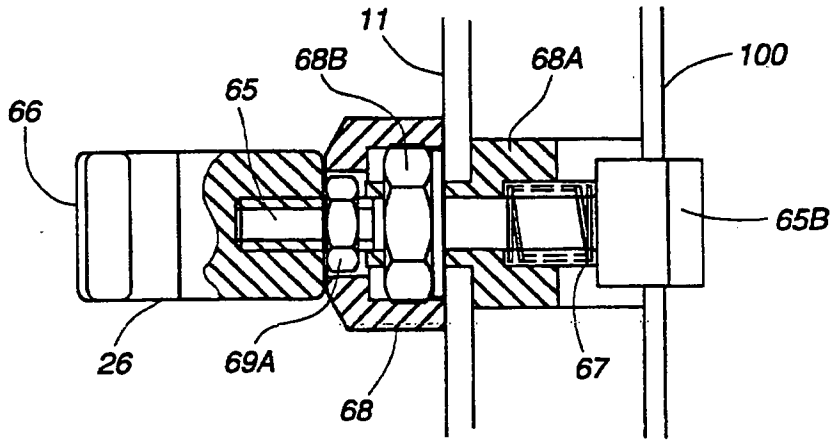
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FIG.2A

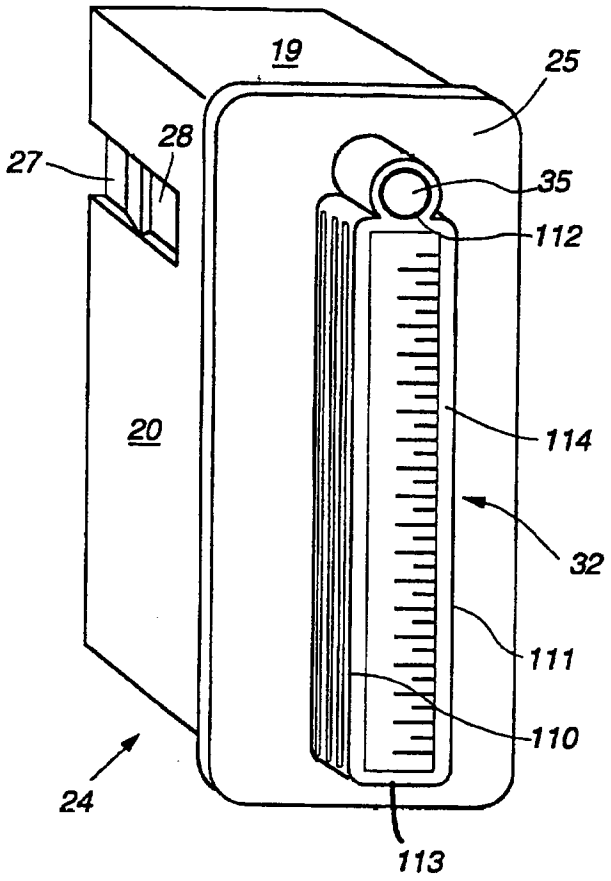
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FIG.3

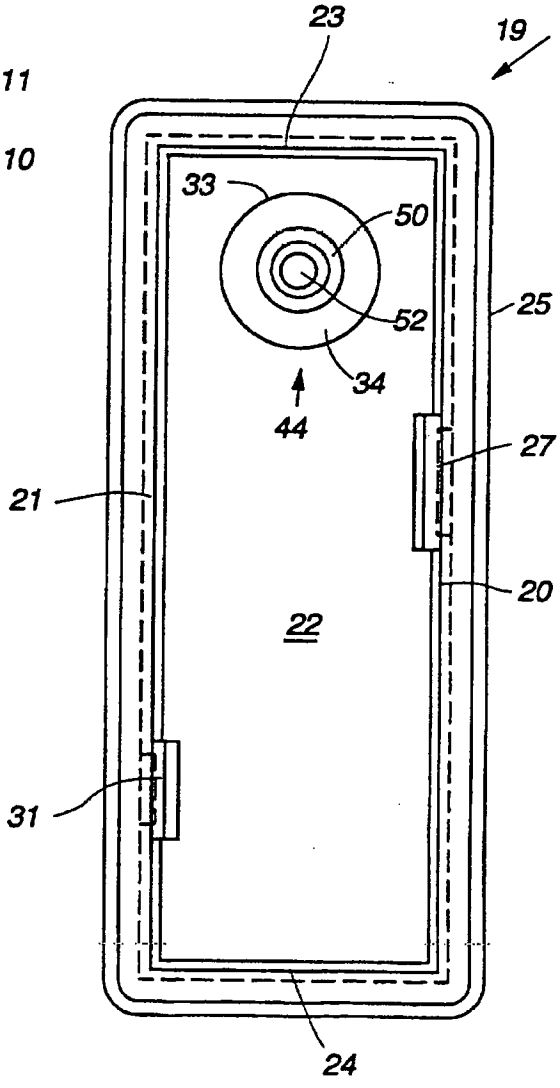
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FIG.4

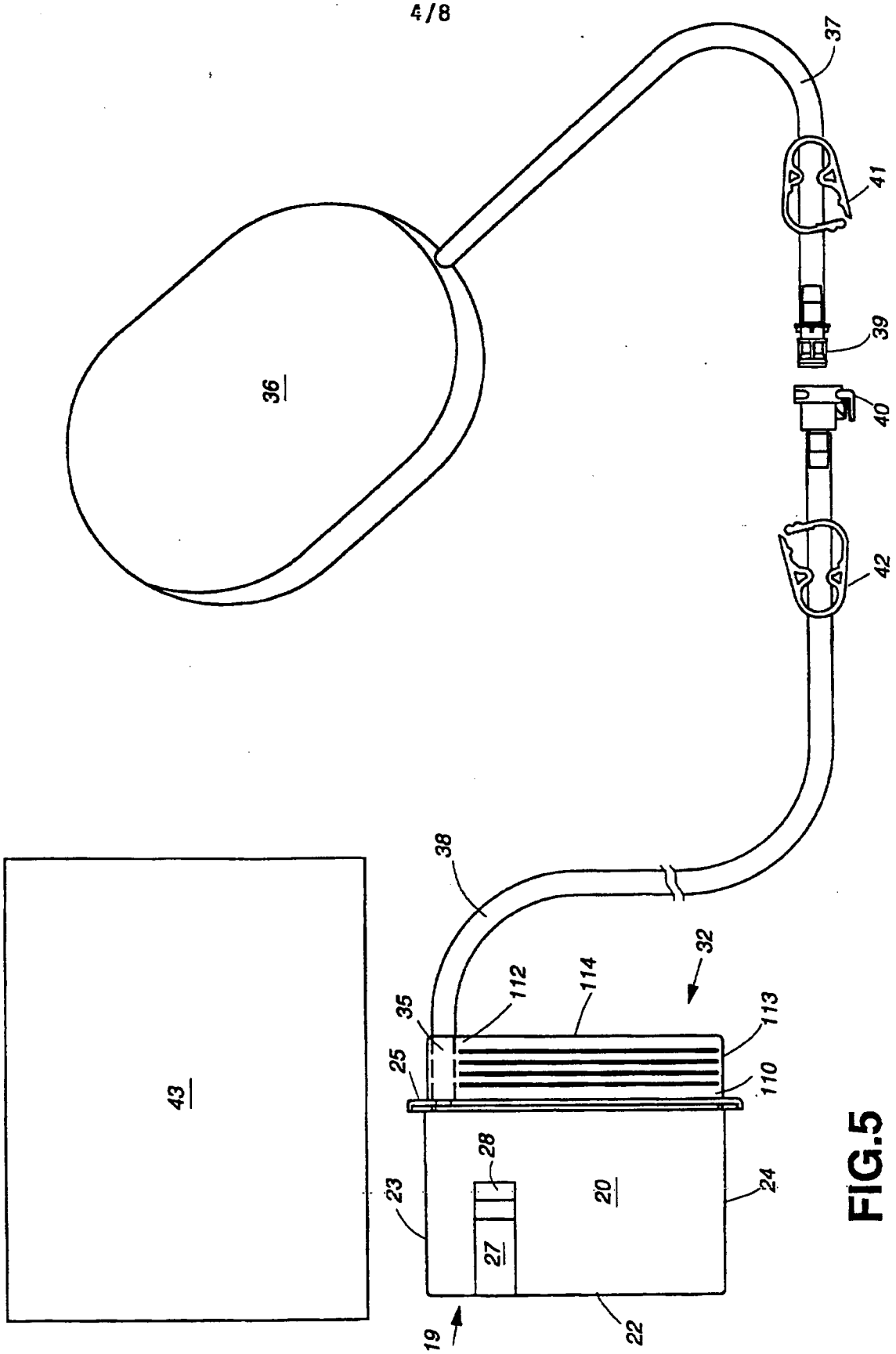


FIG.5

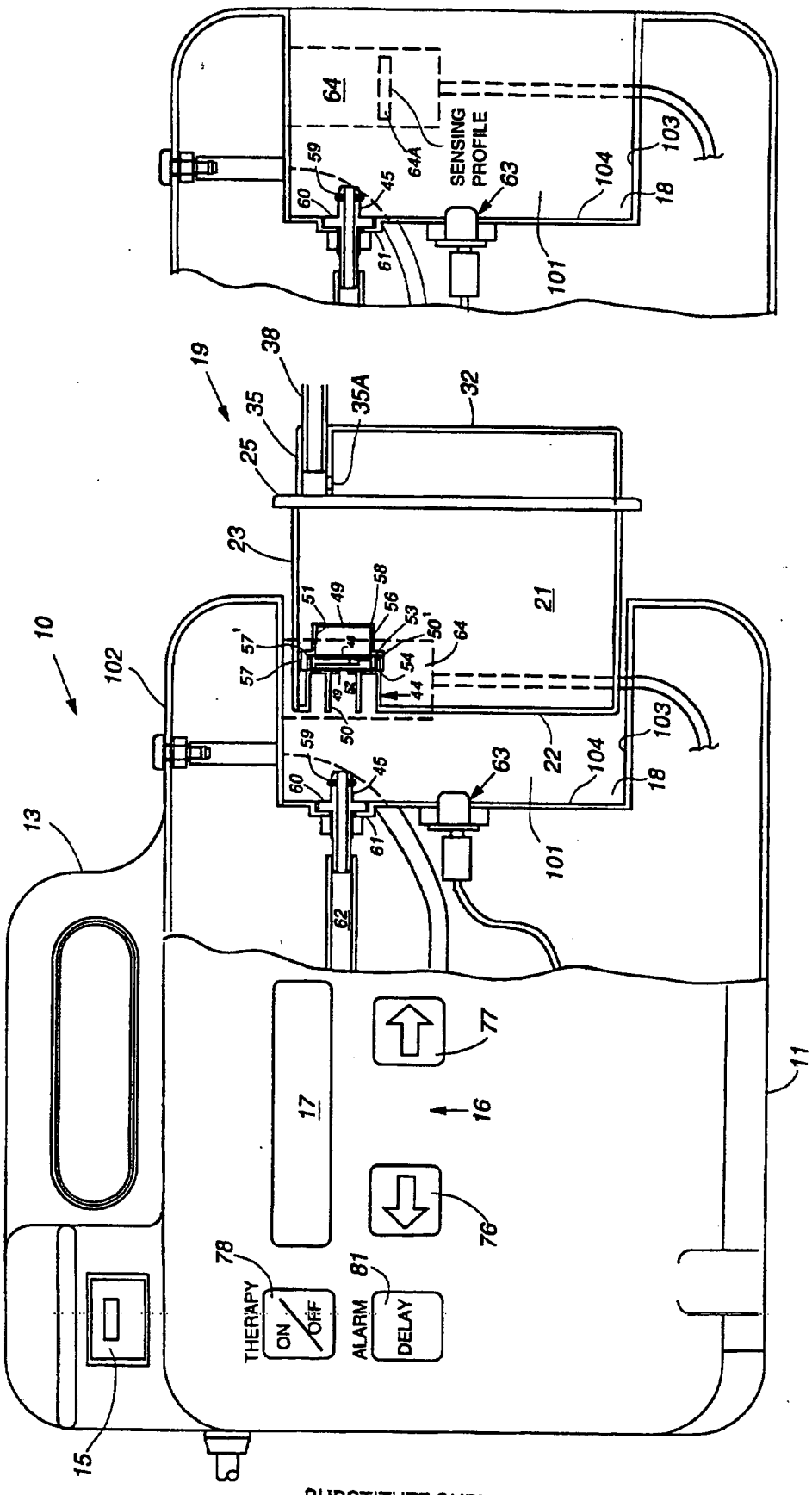
64
SENSING PROFILE
64A
63
59
60
45
61
101
104
103
18
19
38
35
35A
32
25
23
21
51
49
58
56
53
50'
57'
54
44
50
22
62
10
102
13
17
77
16
76
11
15
78
THERAPY
ON
OFF
81
ALARM
DELAY

FIG.6A

FIG.6

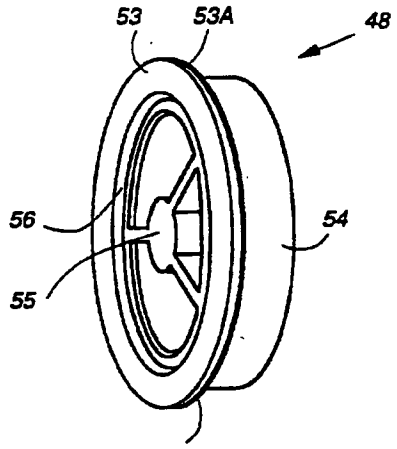


FIG.7

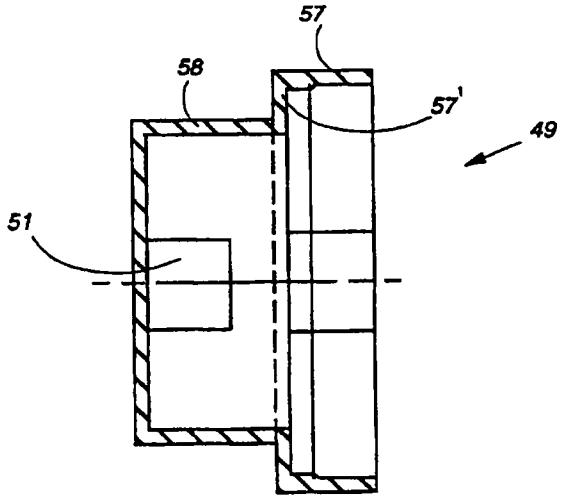


FIG.8

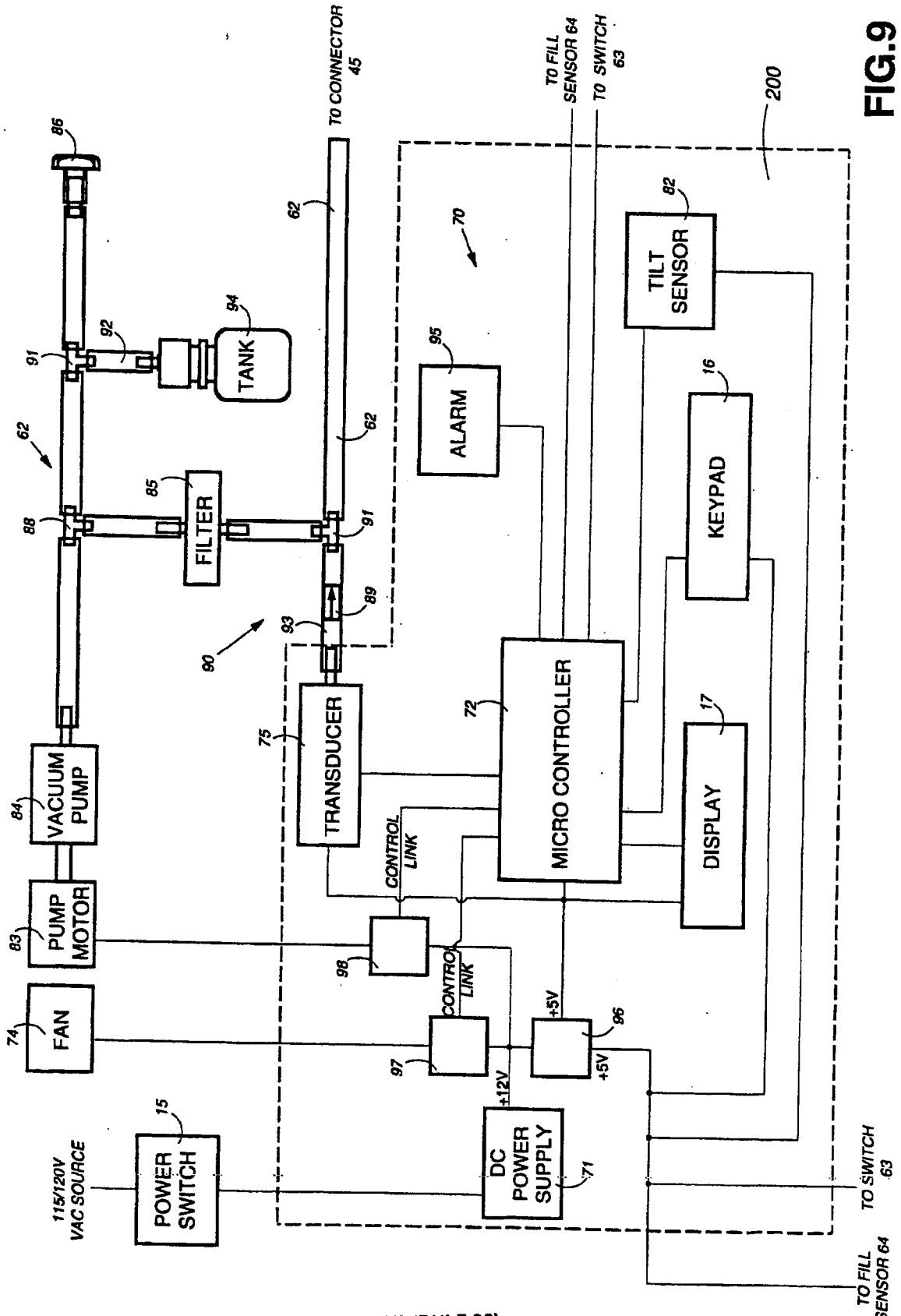
TO CONNECTOR 45
TO FILL SENSOR 64
TO SWITCH 63
200
86
62
70
82
TILT SENSOR
95
ALARM
16
KEYPAD
94
TANK
92
91
62
62
85
FILTER
88
91
89
93
90
75
TRANSDUCER
72
MICRO CONTROLLER
17
DISPLAY
84
VACUUM PUMP
CONTROL LINK
83
PUMP MOTOR
98
CONTROL LINK
+5V
96
74
FAN
97
+5V
±12V
15
115/120V VAC SOURCE
POWER SWITCH
DC POWER SUPPLY
71
TO SWITCH 63
TO FILL SENSOR 64

FIG.9

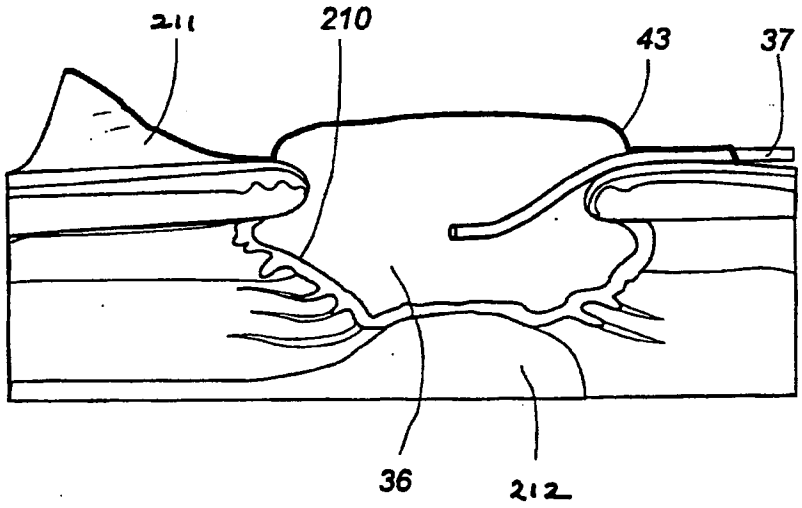


FIG.10

# INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/GB 95/01983

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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|---|---|---|
| X<br>Y | US,A,3 520 300 (FLOWER GUILES JR) 14 July 1970<br>see column 2, line 10 - column 3, line 16; figures<br>--- | 1,7-13, 16-19<br>2-6,14, 15,22-24 |
| Y<br>A | US,A,4 758 220 (SUNDBLOM LEIF J ET AL) 19 July 1988<br>see abstract; figures 3,6A<br>see column 5, line 3 - line 34<br>see column 12, line 48 - line 50<br>--- | 3,4,14, 15<br>5 |
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| A | US,A,5 279 550 (HABIB MAGDI F ET AL) 18 January 1994<br>see abstract; figures 1,3<br>---<br>-/-- | 15 |

[X] Further documents are listed in the continuation of box C.

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| 9 November 1995 | 23. 11. 95 |
| **Name and mailing address of the ISA**<br>European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+ 31-70) 340-3016 | **Authorized officer**<br>Zeinstra, H |

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Int. ..onal Application No
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| A | see column 2, line 26 - column 4, line 34 | 1 |
| Y | GB,A,2 197 789 (SMITHS INDUSTRIES PUBLIC LIMITED COMPANY) 2 June 1988<br>see abstract; figures<br>see page 5, line 1 - line 13 | 22 |
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| Y | PATENT ABSTRACTS OF JAPAN<br>vol. 016 no. 394 (C-0976) ,21 August 1992<br>& JP,A,04 129536 (TERUMO CORP) 30 April 1992,<br>see abstract | 24 |
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Information on patent family members

Int. .onal Application No
PCT/GB 95/01983

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| US-A-5092858 | 03-03-92 | NONE | | |
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| | | JP-T- | 7501958 | 02-03-95 |

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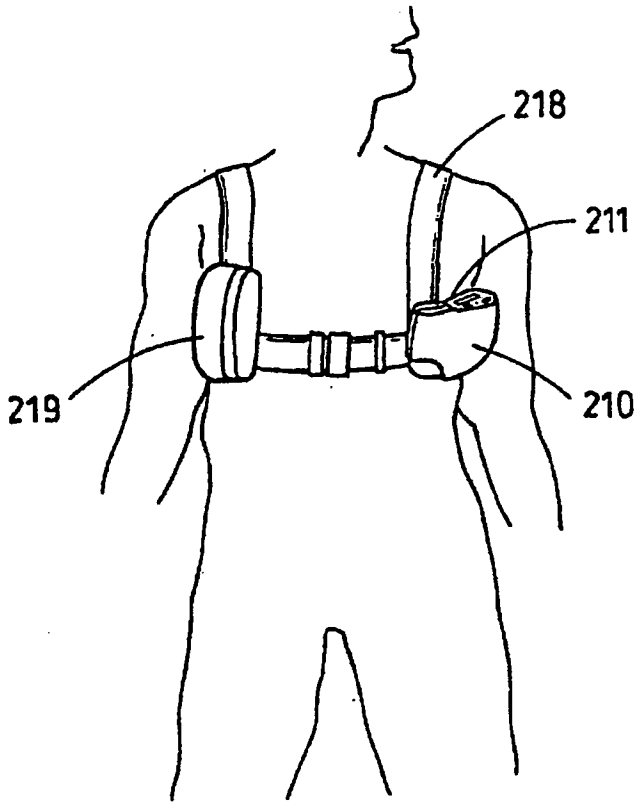
(54) Title: PORTABLE WOUND TREATMENT APPARATUS

(57) Abstract

The invention relates to a portable wound treatment apparatus for stimulating the healing of superficial wounds. The apparatus comprises a housing (210) containing a suction pump and a canister for containing fluids drawn from the wound. The housing is supported on a harness or belt (216, 218) worn by the patient and is connected to a porous dressing at the wound site by a catheter.



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# PORTABLE WOUND TREATMENT APPARATUS

This invention relates to the healing of wounds and, more particularly, to apparatus for stimulating the healing of superficial wounds.

PCT Application No. GB95/01983 (WO 96/05873) describes apparatus for stimulating the healing of wounds comprising a porous pad which is permeable to fluids for introduction into the wound, a dressing for covering the wound and providing an air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound to draw fluids therefrom, and a canister for collecting fluids sucked from the wound. The apparatus described in the above application has proved to be clinically effective but there are some limitations in its use.

The apparatus described in the above PCT application is effective for treating a wide variety of different types and sizes of wounds. However, it may require the patient to undergo treatment on the apparatus for a long period. In cases where the patient is confined to bed this may not be a major problem, but where the patient is mobile it means that he or she would be confined for long periods while the treatment takes place.

An object of this invention is therefore to provide apparatus which can be used more conveniently, especially by patients who are reasonably mobile, and which has certain further advantages which will become apparent from the following description.

According to one aspect of the present invention there is provided a portable therapeutic apparatus for stimulating the healing of superficial wounds in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including

means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

Typically, the housing will have a curved surface on the side intended to be supported against the person's body so as to make the apparatus more comfortable to wear. In addition, controls and indicators indicating the status of the treatment being applied to the wound are preferably located on the upper side of the housing so that the patient can easily see, e.g. the level of suction pressure being applied and the programme for such treatment.

The suction pump is conveniently driven by an electric motor and batteries for such motor may be contained within the housing. However, it is generally more convenient to provide a separate housing for the batteries since these can be placed on the belt or harness in such a way as to balance the weight of the housing, preferably in a housing shaped similarly to the housing for the pump and canister. The canister should be removably mounted within the housing, e.g. by means of a latch or similar release mechanism, so that the canister can be readily removed and replaced when full.

In a portable therapeutic apparatus (in contrast with a static apparatus of the kind described in the above PCT application which cannot be easily carried by the patient), it is less easy to determine the pressure prevailing at the wound site being treated. This is because the pressure will depend, in part, upon the hydrostatic height between the pump and the wound being treated and this height may vary during the treatment, depending upon the patient's movements. Apparatus in accordance with the invention overcomes this problem by providing an additional conduit connecting the wound site or an area close thereto to a pressure-detecting means, preferably located in the housing. The pressure-detecting means can be linked to a microprocessor programmed to maintain such pressure within a

predetermined range irrespective of the movement of the patient. This can be done by, for example, signalling the pump to increase its speed where the hydrostatic pressure increases between the pump and the wound site or, conversely, reducing its speed where the hydrostatic pressure is reduced. This feature can also be used in a static therapeutic apparatus of the kind described in the above-mentioned PCT application.

In the apparatus described in the above PCT application, the level of liquid in the canister is monitored by capacitance measurement. It has now been found that a simpler way of determining when the canister is filled is by measuring or detecting the pressure drop across the canister. The pressure drop can be increased by providing a filter barrier in the region of the outlet end of the canister. Thus, when the liquid reaches a level within the canister so as to substantially occlude the filter, a sharp pressure change occurs in the conduit between the canister and the pump. By monitoring this pressure change, the point at which the canister is filled can be accurately determined.

Additional advantages and features of the present application will become apparent from the following description and accompanying drawings, in which:-

Figure 1 is a schematic layout of the apparatus in accordance with the invention,

Figure 2A and B are pictorial representations of the housing of the pump and canister,

Figure 3A and B are pictorial representations of the apparatus supported on a belt and harness respectively,

Figure 4 is an exploded view of the housing showing the contents,

Figures 5A to F show various views of a preferred form of the canister and a section of a multi-lumen tube, and

Figures 6A to D show various views of a foam dressing connector for connecting the housing to the dressing,

Figure 6E shows a section of a modified multi-lumen tube,

Figures 7A & 7B show a plan and perspective view of a surgical drape for use with the apparatus.

Referring to the drawings, the portable therapeutic apparatus comprises a housing 210 (best shown in Figures 2A and 2B), having rounded corners and a side 211 which is concavely curved in order to fit comfortably to the wearer's body. The shaping of the housing with curved surfaces is to avoid sharp corners or edges which could dig in to the user or his carer. The upper surface 212 is generally flat and has an LCD screen 213 on which details such as applied pressure can be displayed. Control buttons 214 are provided to adjust pressures and treatment intervals. Provision is made for housing a canister within the housing and a snap release cover 215 is arranged for removing or introducing the canister.

Figures 3A and 3B show schematically ways in which the housing 210 may be supported on the patient's body. In Figure 3A the housing 210 is supported on a belt 216 and its weight is balanced by a similarly rounded casing 217 containing a rechargeable battery pack. Figure 3B shows an alternative arrangement in which the housing is supported on a harness 218 and again a battery pack is contained in a housing 219, also supported on the harness.

Figure 4 shows an exploded view of the housing 210 indicating the main components within the housing. The housing consists of front and rear shell mouldings 1 and 2 having an external belt clip 21 for attachment to a belt or harness.

Within housing shell 1 is located a suction pump 6 with associated electric motor 6A and the pump is connected by a silicon rubber tube 103 to a canister

spigot 7A in a compartment 20 for the canister 100. Also connected to a second canister spigot 7B via a tube 10 is a pressure relief valve 8 and both tubes 103 and 10 are connected via T-connectors T to pressure transducers (not shown). A microprocessor 4 is mounted on a PCB board 5 and a membrane assembly 3 incorporates an LCD indicator and control buttons.

The apparatus may include means for recording pressures and treatment conditions given to a particular patient which may be printed out subsequently by the physician. Alternatively, the equipment may include a modem and a telephone jack so that the conditions under which the patient has been treated can be interrogated by the physician from a distant station.

Canister 100 is a push fit into the cavity 20 and its lower end is supported in a cover 30. The cover 30 incorporates fingers 31 which are releasably engageable with lips 32 to hold the canister in position. The canister and the latch mechanism is arranged so that when the latch is engaged, the spigots 7A and 7B are in sealing engagement or abutment with tubular protrusions 33 and 34 formed in the top of the canister.

The method of operation of the apparatus can be appreciated from the schematic layout in Figure 1, in which the canister 100 is connected via tube 101 to a porous dressing 102 at the wound site. Suction is applied to the wound site via the canister by a tube 103, connected to the pump 6. The pressure in the tube 103 is detected by the transducer 105.

A second tube 106 is connected to the wound site 102 at one end, and also to a pressure relief valve 8 and to a second transducer 108. Tubes 106 and 101 can be combined in a multi-partitioned tube in manner to be described later. By means of tube 106 and transducer 108 the pressure at the wound site can be measured or monitored. A filter 109 is placed at or close to the outlet end of the

canister 100 to prevent liquid or solid particles from entering the tube 103. The filter is a bacterial filter which is hydrophobic and preferably also lypophobic. Thus, aqueous and oily liquids will bead on the surface of the filter. During normal use there is sufficient air flow through the filter such that the pressure drop across the filter is not substantial.

As soon as the liquid in the canister reaches a level where the filter is occluded, a much increased negative pressure occurs in tube 103 and this is detected by transducer 105. Transducer 105 is connected to circuitry which interprets such a pressure change as a filled canister and signals this by means of a message on the LCD and/or buzzer that the canister requires replacement. It may also automatically shut off the working of the pump.

In the event that it is desired to apply intermittent suction to the wound site, a pressure relief valve 8 enables the pressure at the wound site to be brought to atmospheric pressure rapidly. Thus, if the apparatus is programmed, for example, to relieve pressure at 10 minute intervals, at these intervals valve 8 will open for a specified period, allow the pressure to equalise at the wound site and then close to restore the suction. It will be appreciated that when constant suction (or negative pressure) is being applied to the wound site, valve 8 remains closed and there is no leakage from atmosphere. In this state, it is possible to maintain negative pressure at the wound site without running the pump continuously, but only from time to time, to maintain a desired level of negative pressure (i.e. a desired pressure below atmospheric), which is detected by the transducer 105. This saves power and enables the appliance to operate for long periods on its battery power supply.

Instead of running two separate tubes to the wound site, it is preferable to contain tubes 106 and 101 in a single tube which is connected through the canister. Thus, for example, tubes 103 and 101 may comprise an internal tube surrounded by

an annular space represented by tube 106. This is illustrated in Figures 5A to 5F and in a modified form in Figure 6E.

In an alternative embodiment, the multi-lumen tube may be constructed as shown in Figure 6E. In this embodiment, the internal bore 606 comprises the line 101 (see Figure 1) and is used to extract fluids from the wound site. Air flow (represented by line 106 in Figure 1) passes down conduits 607 located within the walls of the tube. By spacing the conduits 607 at 90° intervals around the tube, the risk of arresting the air flow by kinking or twisting the multi-lumen tube is minimised.

Figure 5E is a plan view of the top of a preferred shape of canister, the generally triangular shape in section being chosen to fit better the space within cavity 20 (see Figure 4). Tubular protrusions on the top of the canister are connected internally of the canister with respectively conduits 124 and 121 (see sectional view of Figure 5B), thus maintaining a separation between the tubes which are represented by lines 103 and 106 in Figure 1. At the base of the canister, a moulding 125 facilitates connection to a multi-partitioned tube 126 shown in Figure 5F. Tube 126 has a central bore 127 which is sized to fit over a spigot 128 in moulding 125. At the same time, the external wall of tube 126 seals against the inner wall 129 of moulding 125. Thus, compartment 124 will connect with central bore 127 and the compartment 121 will connect with the annular spaces 130 of tube 126. In this way, a conduit 130 corresponds with line 106 and central bore 127 with line 101 as shown in Figure 1.

The partitioned tube need not continue all the way to the wound site 102, but can be connected to a short section of single bore tube close to the wound site.

In the event of an air leak in the dressing at the wound site 102, this can be detected by both transducers 105 and 108 reading insufficient negative pressure for

a specific time period, and then triggering a leak alarm, i.e. a message on the LCD, preferably also with an audible warning.

Typically, the pump 6 is a diaphragm pump but other types of pumps and equivalent components to those specifically employed may be substituted.

Figures 6A~6D show various views of a connector for attaching the multi-lumen tube at the wound site. Figures 7A and 7B show a plan and perspective view of a surgical drape for attaching the connector to a porous dressing at the wound site. The connector comprises a moulded plastics disc-like cup 601 having a centrally positioned spout 602. The spout 602 is sized to accept, as a closely sliding fit, the end of a multi-lumen tube e.g. of the kind shown in Figures 5F or 6E. In use, a porous dressing is cut to correspond with the extent of the wound and pressed onto the wound as shown in Figure 10 of our above cited PCT application WO 96/05873. Instead of introducing the lumen into the foam dressing, the cup 601 is pressed onto the porous dressing and secured by a surgical drape. However, if desired, the end of the lumen can be passed into the spout and additionally pressed into the foam. A surgical drape such as shown in Figures 7A and 7B, can be used to secure the connector, lumen and dressing. The drape comprises a polyurethane film 701 coated on one side with a pressure-sensitive acrylic resin adhesive. A hole 702 is cut through all layers of the drape and the hole is dimensioned to correspond approximately with the outer cross-section of the spout 602. Film 701 has an overall size which allows it to be adhered to the patient's skin around the wound site, while at the same time, securing the connector to the porous dressing. A sufficient overlap around the wound is provided so that an air-tight cavity is formed around the wound.

In an alternative form, the drape can be made in two parts, e.g. by cutting along the line X-X in Figure 7A. With this arrangement, the wound can be sealed

by overlapping two pieces of surgical drape so that they overlap each other along a line Y-Y as shown in Figure 6D.

The surgical drape may include a protective film 703, e.g. of polyethylene, and a liner 704 which is stripped off prior to use to expose the pressure-sensitive adhesive layer. The polyurethane film may also include handling bars 705,706, which are not coated with adhesive, to facilitate stretching of the film over the wound site. The dressing is preferably a pad of porous, flexible plastics foam, e.g. reticulated, open intercommunicating cellular flexible polyurethane foam, especially of the kind described in the above-mentioned PCT application WO 96/05873.

Alternatively, a reticulated intercommunicating cellular foam made from flexible polyvinylacetate or polyvinylalcohol foam may be used. The latter is advantageous because it is hydrophilic. Other hydrophilic open celled foams may be used.

In another method of therapy, the foam dressing may be sutured into a wound after surgery and the foam dressing connected to the pump unit by the multi-lumen catheter. Negative pressure can then be applied continuously or intermittently for a period determined by the surgeon, e.g. from about 6 hours to 4 to 5 days. After this period, the dressing is removed and the wound re-sutured. This therapy improves the rate of granulation and healing of wounds after surgery.

CLAIMS:-

1. A portable therapeutic apparatus for stimulating the healing of a superficial wound in a person, which comprises a housing containing a suction pump and a canister for containing fluids drawn from the wound by said pump, said canister including means for connection to a dressing in the region of the wound and a harness or belt for supporting the housing on the person.

2. Apparatus as claimed in claim 1 wherein the housing has a curved surface on the side intended to be supported against the person's body, and controls located on an upper side of the housing.

3. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that suction can be applied to the wound to draw liquids therefrom, said tube being connected to the pump via a canister for collecting liquids sucked from the wound and a filter barrier located in the canister at the outlet side, and pressure detecting means arranged to detect pressure changes in the tube between the canister and the pump and to signal a pressure change when liquid in the canister covers a substantial part of the filter barrier, thus indicating a full canister.

4. Apparatus as claimed in claim 3 wherein the filter barrier covers the entire outlet from the canister and the dimensions of the pores in said barrier are such that when liquid covers substantially the whole of the filter barrier, said pressure detecting means signals a sharp increase in negative pressure in the tube connecting the canister with the pump.

5. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that suction can be applied to the wound to draw liquids therefrom, said tube being connected to the pump via a canister for collecting liquids sucked from the wound and at least one filter interposed between the canister and the pump, said apparatus including an additional conduit connecting the porous pad to pressure detecting means whereby the pressure substantially at the wound site can be monitored.

6. Apparatus as claimed in claim 5 which includes a relief valve for admitting air to the additional conduit and means for controlling the operation of the valve so that intermittent suction can be applied to the wound site.

7. Apparatus as claimed in claim 5 or 6 in which a single tube links the porous pad with the housing, said tube being longitudinally partitioned to provide a conduit for applying suction and an additional conduit for connection to said pressure detecting means.

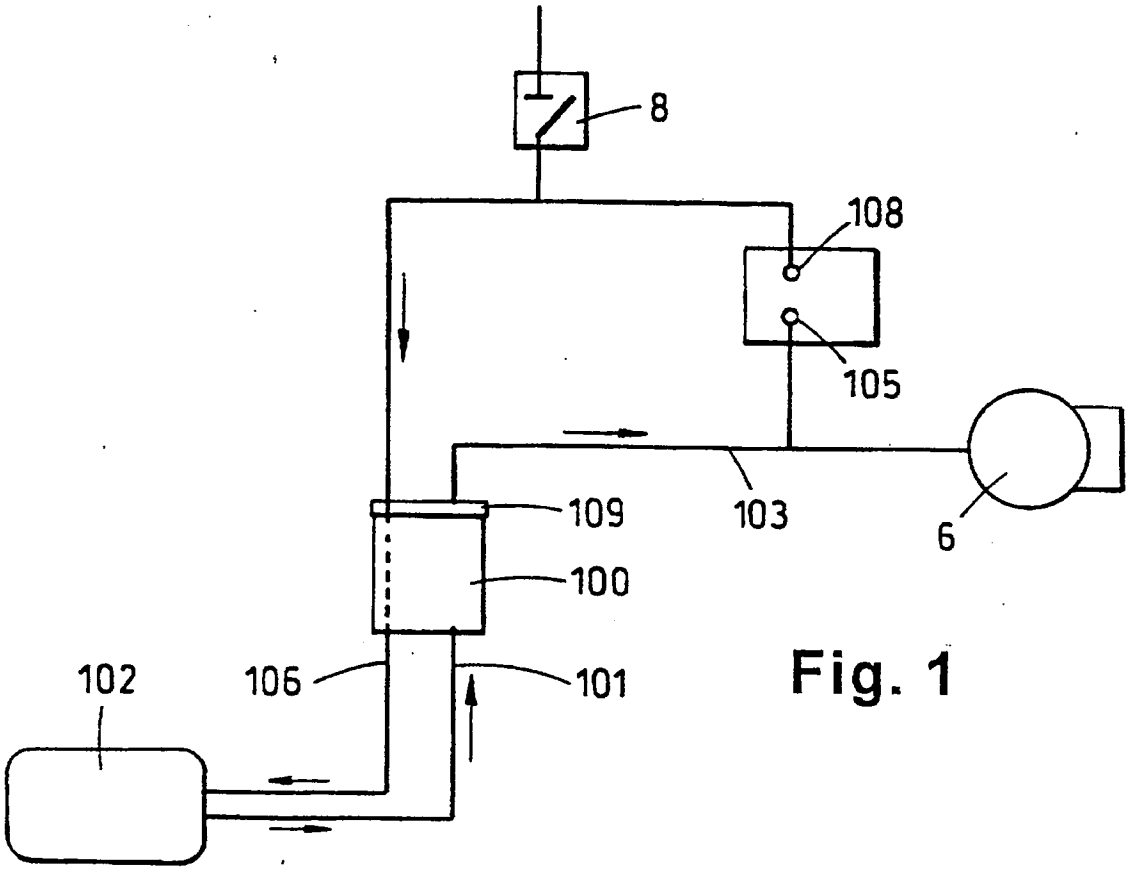


Fig. 1

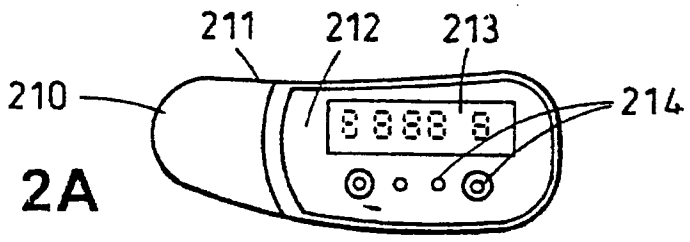


Fig. 2A

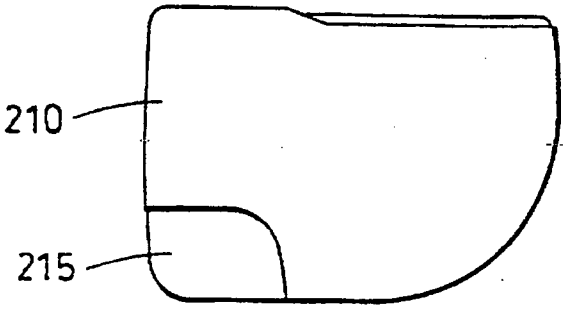


Fig. 2B

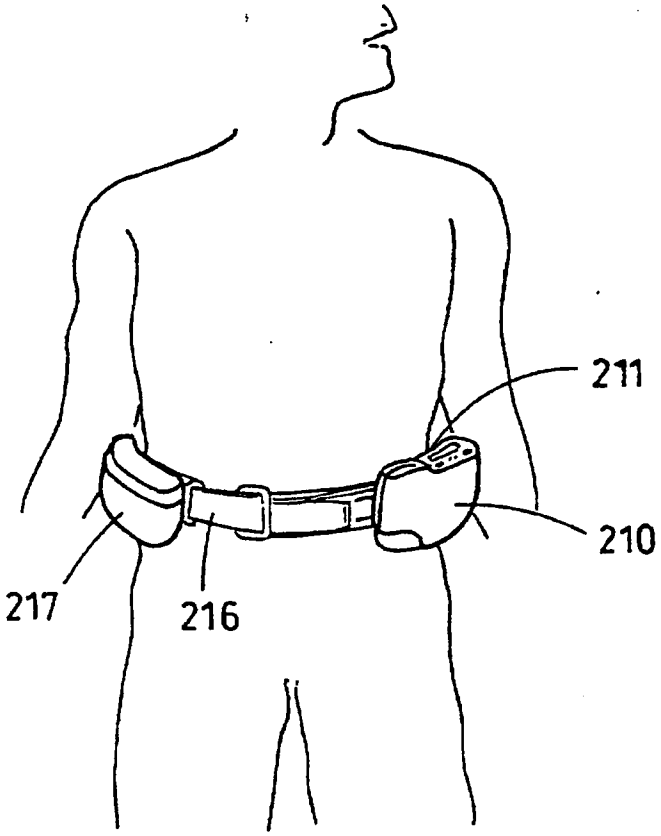


Fig. 3A

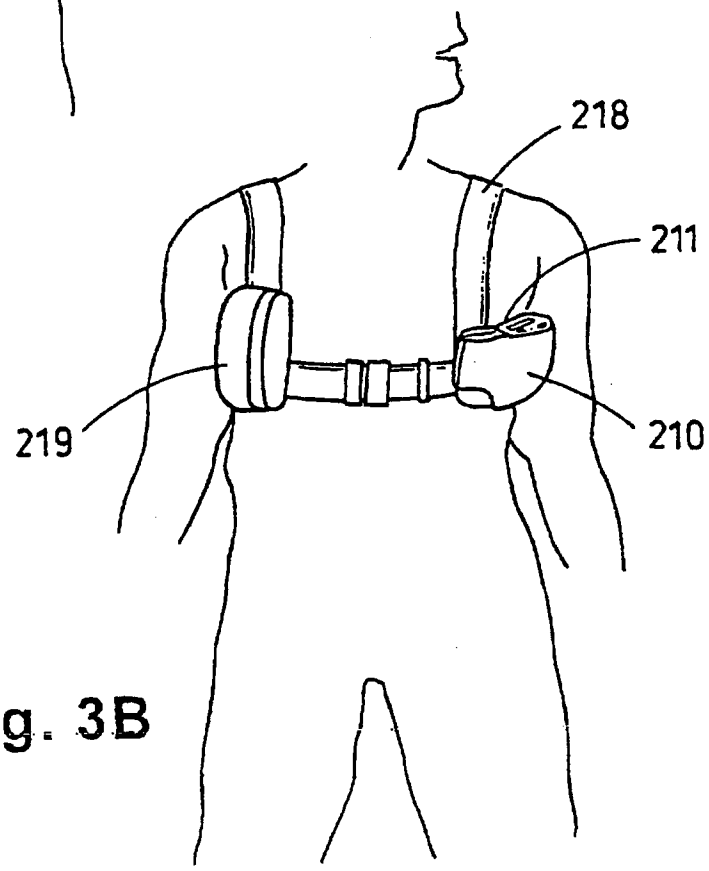


Fig. 3B

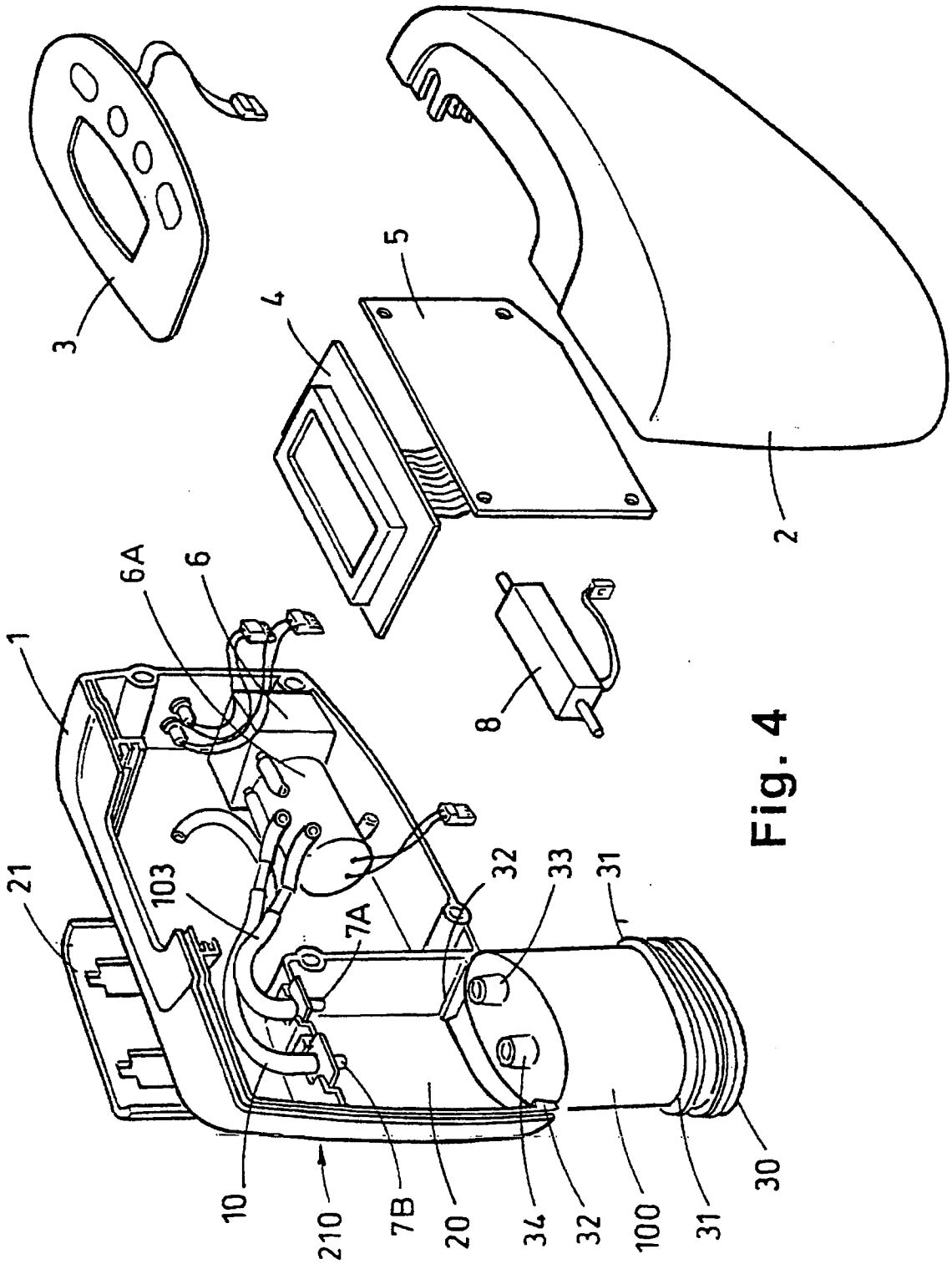


Fig. 4

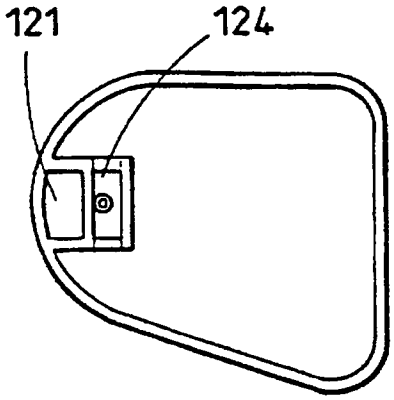


Fig. 5A

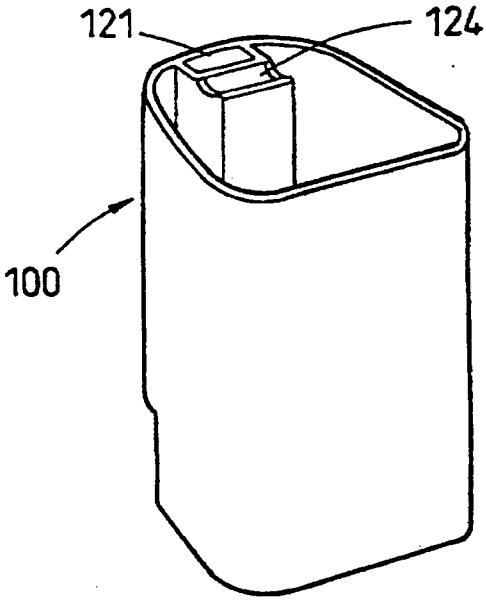


Fig. 5D

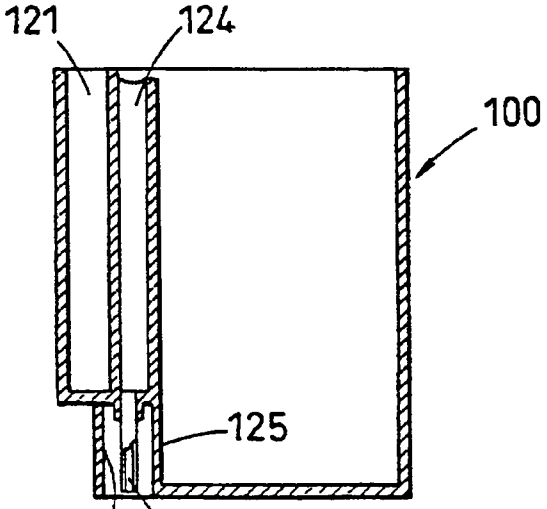


Fig. 5B

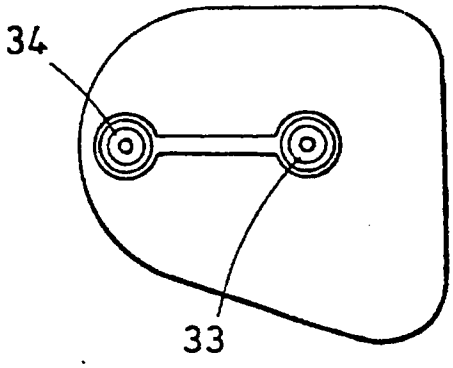


Fig. 5E

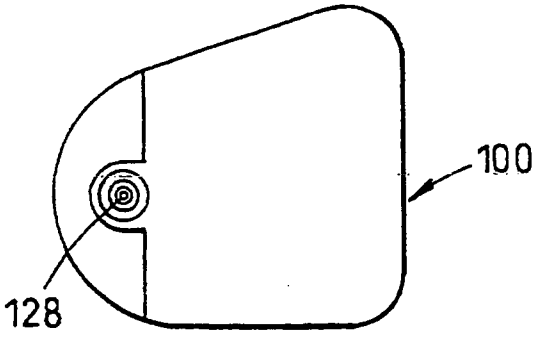


Fig. 5C

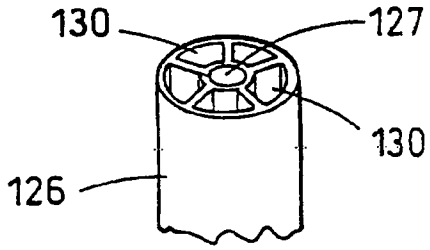


Fig. 5F

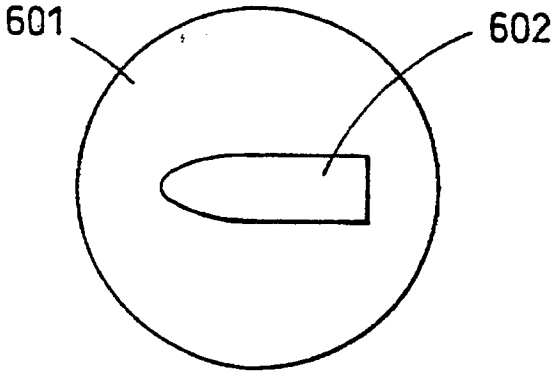


Fig. 6A

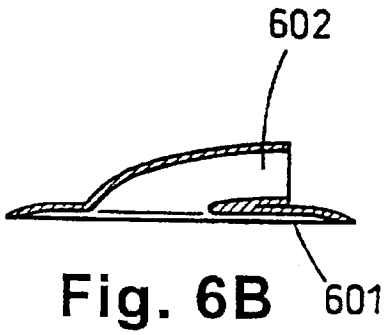


Fig. 6B

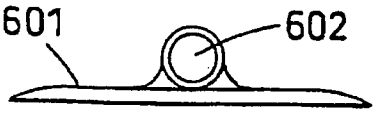


Fig. 6C

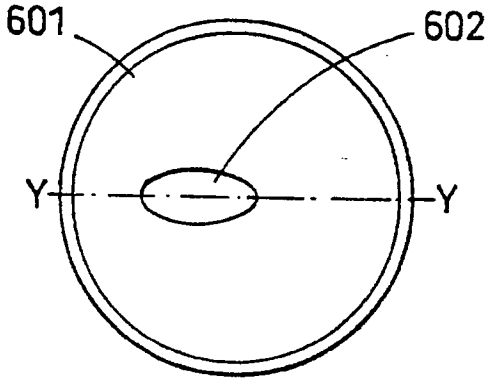


Fig. 6D

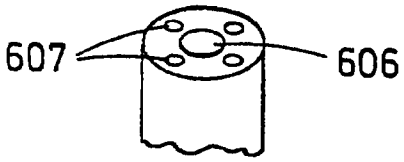


Fig. 6E

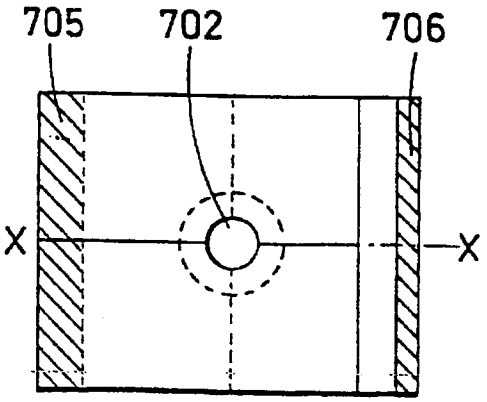


Fig. 7A

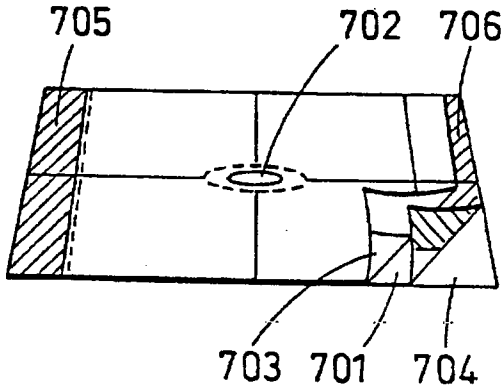


Fig. 7B

I .ational Application No
PCT/GB 96/02802

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M27/00 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 5 134 994 A (SAY) 4 August 1992<br>see column 1, line 7 - line 9<br>see column 2, line 6 - column 4, line 2<br>see figures 1,4-8 | 1 |
| Y | --- | 2 |
| Y | WO 80 02182 A (MOSS) 16 October 1980<br>see page 4, line 23 - line 31<br>see figure 1 | 2 |
| X | --- | 1 |
| | US 4 710 165 A (MCNEIL ET AL.) 1 December 1987<br>see column 5, line 1 - line 56 | |
| | --- | |
| | -/-- | |

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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1

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 17 April 1997 | 29.04.97 |

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| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. ( + 31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax ( + 31-70) 340-3016 | Schönleben, J |

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | WO 94 20041 A (WAKE FOREST UNIVERSITY) 15 September 1994<br>see page 12, line 8 - page 17, line 8<br>see page 18, line 2 - line 35<br>see figures 1,8 | 3-7 |
| A | | 5 |
| Y | DE 295 04 378 U (MTG) 14 September 1995<br>see the whole document | 3,4 |
| Y | DE 43 06 478 A (WAGNER) 8 September 1994<br>see column 2, line 8 - line 16<br>see column 4, line 66 - column 5, line 65<br>see figures 1-5 | 5-7 |
| A | GB 2 220 357 A (SMITHS INDUSTRIES) 10 January 1990<br>see page 7, line 1 - page 8, line 20<br>see figure 1 | 3 |
| A | GB 2 235 877 A (ANTONIO TALLURI) 20 March 1991<br>see page 4, line 12 - page 5, line 18<br>see figures 2-4 | 3 |
| A | US 3 066 672 A (CROSBY ET AL.) 4 December 1962<br>see column 1, line 67 - column 2, line 35<br>see figures 1,3 | 6 |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 96/02802

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

SEE ANNEX

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

National Application No
PCT/GB 96/02802

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 5134994 A | 04-08-92 | NONE | |
| WO 8002182 A | 16-10-80 | US 4266545 A | 12-05-81 |
| | | EP 0026226 A | 08-04-81 |
| | | JP 56500360 T | 26-03-81 |
| US 4710165 A | 01-12-87 | NONE | |
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| | | EP 0688189 A | 27-12-95 |
| DE 29504378 U | 14-09-95 | NONE | |
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| | | EP 0692987 A | 24-01-96 |
| GB 2220357 A | 10-01-90 | EP 0358302 A | 14-03-90 |
| GB 2235877 A | 20-03-91 | NONE | |
| US 3066672 A | 04-12-62 | NONE | |

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9719520.0 12 September 1997 (12.09.97) GB

(71) Applicant *(for all designated States except US)*: KCI MEDICAL LIMITED [GB/GB]; Two Rivers, Station Lane, Witney, Oxfordshire OX8 6BH (GB).

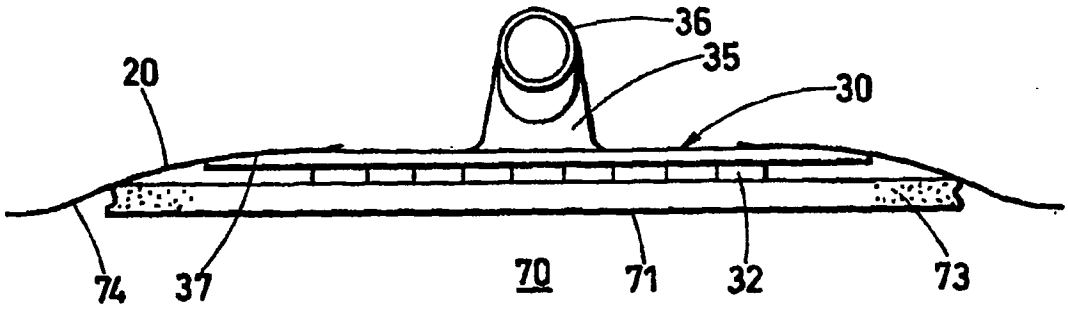
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: HEATON, Keith, Patrick [GB/GB]; 33 Hermitage Road, Poole, Dorset BH14 0QG (GB). HUNT, Kenneth, William [GB/GB]; 18 Egdon Drive, Merley, Wimborne, Dorset BH21 1TY (GB).

(74) Agent: WOODCRAFT, David, Charles; Brookes & Martin, High Holborn House, 52/54 High Holborn, London WC1V 6SE (GB).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DE (Utility model), DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published**
*With international search report.*

(54) Title: SURGICAL DRAPE AND SUCTION HEAD FOR WOUND TREATMENT




(57) Abstract

This invention relates to surgical drapes and in particular provides a drape and suction head combination for attaching the suction head to a wound area. The suction head comprises a planar flange portion and a tubular connector piece on a first face which communicates with an aperture extending to the second face. The second face is formed with projections which define flow channels for facilitating flow of liquids to the aperture.

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# Surgical Drape and Suction Head for Wound Treatment

This invention relates to surgical drapes and suction heads for wound treatment.

Surgical drapes are widely used in surgical operations for the purpose of reducing infection and facilitating the handling of skin around incisions. Normally, they are transparent or translucent. Typically, they consist of a flexible, plastics film which is adhesive-coated and which is applied to the area of the operation, prior to making the incision. Surgical drapes are also used for attaching treatment devices to patients after an operation, such as catheters or drainage tubes.

A further, recently developed use is for connecting a suction tube to a wound for the purpose of stimulating healing of the wound. Such use is described in our earlier PCT Applications Nos. WO 96/05873 and WO 97/18007.

Various proposals have been made in the past to design the surgical drape so that handling of the sticky, flexible, plastics film is facilitated. For example, US Patent No. 5,437,622, describes a surgical drape which is a laminate of three materials. The first material comprising a transparent, thin plastics film which is adhesive-coated and this is protected with a layer of release-coated paper. The other face of the adhesive-coated film is strengthened with a reinforcing layer of a less flexible, plastics film. Handling bars or strips are attached to the flexible, plastics film at its lateral edges to facilitate handling of the flexible, plastics film after stripping away the protective releasable layer.

Where it is desired to use a surgical drape primarily to attach a device such as a catheter to a wound area after an operation or for long term treatment, it is inconvenient for the surgeon or nurse to have to adapt a standard surgical drape for this purpose. It would be more convenient to have a surgical drape which was suitable without adaptation to accommodate the treatment device.

One aspect of the present invention is directed to a solution to this problem. A second aspect provides a combined surgical drape and suction head for applying suction to a wound area to facilitate application of negative pressure therapy.

According to one aspect of the present invention there is provided a surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the adhesive coating, the drape having an aperture through at least the strengthening and adhesive-coated film to permit, in use, access to a wound area, a first edge of the drape having non-adhesive coated handling bars for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries a flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use. Preferably, non-adhesive-coated handling bars are positioned at opposite lateral edges of the drape.

In practice, surgical drapes may be manufactured by laminating an adhesive-coated flexible film, such as a polyurethane film, to a protective releasable layer, such as a siliconised paper. A strengthening layer of thicker plastics material, e.g. a polyolefin such as polyethylene, may be applied to the non-adhesive coated face of the flexible film, so that a three-layer laminate is produced. These laminates are produced in substantial width and may be slit longitudinally to the desired width and then laterally to form drapes of the desired size.

After slitting to a desired width, handling bars are normally applied to the adhesive-coated layers at one or both lateral edges to facilitate separation of the film

from the protective, releasable layer. While an aperture could be cut at the desired position through the layers to accommodate a catheter or a device such as those described in our above-mentioned applications, it is difficult to handle the highly pliable and adhesive film after the releasable layer has been stripped off.

Although the strengthening layer does somewhat improve the handling characteristics, this is not a complete answer to the problem. However, the handling characteristics are substantially improved by providing a protective layer which is in at least two portions, one of which is in the form of a strip, e.g. one extending parallel to the lateral edges of the drape, and covering the peripheral area around the aperture through the drape. By providing a flap on this portion of the releasable layer, it can be stripped off initially so that the drape is first positioned around the device which is to pass through the aperture, and then the remaining part of the protective releasable layer is stripped off to adhere the drape to the patient's skin around the area to be treated.

In a preferred form of the invention in which negative pressure therapy is applied to a wound area, the surgical drape described above is combined with a suction head having a connector piece which is adapted to be connected to a suction tube. Thus, in this embodiment, the suction head can be adhered to the patient's skin in the area of the wound after removing the strip of protective releasable layer, and then the remaining part of the drape affixed to the patient's skin. In this way, the suction head is held firmly in place and, at the same time, seals the suction head to the wound area and prevents leakage of air from atmosphere into the wound area.

The invention also includes a suction head having a design which facilitates the suction of fluid from a wound area.

According to a further feature of the invention, therefore, there is provided a suction head for applying suction to a wound area which comprises a generally planar

flange portion and a tubular connector piece on a first face, for connecting a suction tube to an aperture through the flange portion to the other face, said other face having projections defining flow channels facilitating flow of fluid towards said aperture.

Preferably, the suction head described above is combined with a surgical drape, the drape comprising a thin, flexible, adhesive-coated plastics film, and the tubular connector piece extends through an opening in the plastics film with the adhesive coating adhered to said first face of the flange portion.

Preferably, the suction head is used in conjunction with an open-celled foam pad so that one surface of the foam pad is placed in contact with a wound area and the suction head applied to the other surface of the foam pad. In the case of deep wounds the foam may be shaped and placed so that it is packed into the wound cavity as described in our above cited PCT applications. According to another technique, which is particularly applicable to superficial wounds, the foam pad may be a relatively thin pad which is placed over the wound. The suction head is placed in contact with the open face of the foam pad and the drape applied over the suction head to fix the assembly to the patent's skin.

Various types of open celled foams can be used as described in our above cited PCT applications. The foam may be a polyurethane foam but polyvinyl acetate (pva) foams are preferred, especially when used as a pad which is placed over the wound. These are to some extent hydrophilic, which seems to exhibit beneficial comfort properties when applied to the skin. Wound healing is stimulated by maintenance of moist conditions in the wound area, and this is facilitated by using a hydrophilic foam.

Further features and advantages of the present invention will be apparent from the following description and accompanying drawings, of non-limiting examples in accordance with the invention.

Referring to the accompanying drawings:-

Figure 1 represents a conventional design of surgical drape;

Figure 2 represents a variation in the design of the handling bars at one end of the drape shown in Figure 1;

Figure 3 is a view similar to Figure 1 of a surgical drape in accordance with the invention;

Figure 4 is a plan view of the surgical drape shown in Figure 3;

Figure 5 is a plan view from beneath of a suction head in accordance with the invention; and

Figure 6 is a side elevation of the suction head shown in Figure 5;

Figure 7 is a view similar to Figure 6 but shows the suction head secured to a skin surface with the drape and with a foam pad located between the head and the skin surface.

Figure 8 is a perspective view of the drape with a central strip portion of the protective sheet in the course of being removed, and

Figures 9(a)~9(c) illustrate the steps of affixing the dressing assembly to a wound area on a patient's leg and attachment to a negative pressure assembly.

Referring to Figures 1 and 2 of the accompanying drawings, a conventional laminate for use as a surgical drape comprises a thin, flexible, transparent plastics film 1 which is adhesive-coated on one face 2, normally with a high-tack pressure-sensitive adhesive, and is protected with a releasable layer 3. The thin plastics film is conveniently of polyurethane because it transmits moisture. Layer 3 is normally considerably thicker than film 1 and is coated on the surface adjacent to the adhesive with a releasable material such as a silicone to facilitate stripping away from the adhesive-coated film.

In order to facilitate removal of the adhesive-coated film prior to use of the device, handling bars 4 are bonded at each end to the adhesive-coated film 1. Thus,

by holding one of the bars 4, the protective layer 3 can be stripped off and the adhesive face applied to the skin of the patient. To facilitate handling of the thin, flexible film 1, a strengthening plastics film 5 is frequently applied to the free face of the plastics film 1. This is generally also transparent or translucent. Film 5 is preferably not bonded with adhesive to film 1, but may remain in contact by reason of electrostatic forces or because of close contact between the two conforming surfaces of film 1 and film 5.

Usually, the surgeon or nurse will wish to strip off the protective layer 5 after the film 1 has been correctly placed on the patient's skin, and this can be facilitated by making partial cuts 6 through the films 1 and 5, so that as the handling bar 4 is drawn upwards from the patient's skin, the adhesive film 1 remains adhered to the patient, while the partial cuts 6 causes separation of the flexible film from the strengthening film 5. Strengthening bars 7 may be provided to hold the lateral edges of the strengthening film 5 and film 1 together with their main parts.

An alternative arrangement is shown in Figure 2, in which the strengthening film 5 is provided with a separate overlapping handling bar 14, to facilitate its removal from the flexible film 1.

Further details of the make-up and manufacture of surgical drapes are given in US Patent No. 5,437,622 and European Patent Application No. 0161865 and the prior art referred to therein, the disclosure of which is incorporated herein.

Referring to Figure 3 and 4, the surgical drape of this invention comprises a protective outer film 20, laminated to a thin, flexible film 21. The flexible film 21 includes an adhesive-coated layer which is protected with a release-coated sheet material 24. Lateral edges of the flexible film 21 are provided with handling bars 23. Thus far, the design is essentially the same as that shown in Figures 1 and 2.

The drape of the present invention differs from the drape shown in Figures 1 and 2 in that an aperture 25 is cut through the strengthening layer 20 and through the flexible layer 21. The other difference compared with the prior art drapes is that the protective releasable layer is formed in at least two sections.

In the embodiments shown in Figures 3 and 4, the central portion of the releasable layer comprises a strip 26, having flaps 27 which overlap the remaining outboard portions of the releasable layer. The purpose of this is to enable the central strip 26 to be removed first, without disturbing the remaining portions of the releasable layer. The drape can then be fitted around the wound area and, if desired, a suction device or other treatment device passed through the aperture 25 and secured to the patient's skin with the peripheral areas of exposed adhesive-coated film.

An example of a device for applying suction to the wound area is illustrated in Figures 5, 6 and 7.

Referring to these Figures, the suction head comprises a flange portion 30 having a tapered edge 31, and a profile which may be of any desired shape but is generally rounded at its edges. On the face of the flange 30 intended for contact with the patient's skin or a foam pad are formed a series of projections 32 which are distributed over the surface of the flange apart from the peripheral edge portion 31. The purpose of these projections is to provide fluid channels 33 facilitating the flow of fluids from any point of the flange to a central point 34, from which it is intended to apply suction. The suction head includes a connector 35, located above the aperture 34, having a tubular end 36 adapted for receiving and connecting a catheter. The tubular end may have an outwardly tapered portion to facilitate feeding a catheter into the connector. The upper surface 37 of the suction head has a substantially smooth surface.

In use, the connector portion 35 is sized so that it extends through the aperture 25 in the surgical drape shown in Figures 3 and 4, with the adhesive surface around the aperture bonded to the smooth surface 37 of the flange 30. The suction head may be packaged in this condition with the surgical drape so that in use, the strip 26 is removed by pulling on the handles 27 thus exposing the adhesive surface in the vicinity of and surrounding the suction head. The suction head can then fixed in the desired position on the patient's wound and then the remaining portion of the protective film removed to fix the drape to the patient. The flange 30 of the suction head may be somewhat oval as shown in Figure 5, and have dimensions as indicated in this Figure, i.e. a longer dimension of about 95mm and a short dimension of about 70mm. Alternatively, the flange may be circular and be smaller in plan view. For example, the diameter of a circular suction head may be from about 30 to 50mm in diameter, e.g. about 40mm. It has been found that the suction head flange should not overlap the area of the wound. Thus, in the case of smaller wounds a smaller suction head is indicated.

Figure 7 shows the suction head attached to a wound area 71 of a patient 70. The suction head is pressed into firm contact with a flexible, open-celled foam 73, which is itself pressed into contact with the wound area 71. The suction head and foam pad are pressed into contact with the wound area by a surgical drape 20 having an adhesive surface 74. The adhesive surface is bonded to the patient's skin outside the periphery of the foam pad and suction head. It is also bonded to upper surface 37 of the suction head. An aperture is formed in the drape to permit the connector portion 35 to extend upwardly through the drape. In order to avert the danger of incorrect catheter tubes being fitted to the connector 35, the latter may have a customised cross-section or internal projection such as a rib or key which co-operates with a corresponding slot or key way in the catheter. Alternatively, the catheter may

be moulded with a projection or longitudinal rib which co-operates with a corresponding slot or key way in the aperture of the connector 35.

The foam pad may be packaged in a plastic pouch, sterilised by gamma irradiation and supplied in the same box or in other packing units as the suction head and drape.

Figures 8 and 9(a)~(b) illustrate the way in which the drape/suction head combination is fitted to a wound on a patient's skin. In Figure 8, a backing sheet 101 having a release coated surface is removed in the first step from the adhesive face 102 of the drape to expose the face of the connector 30. A pad 103 of foam is positioned over the wound area and the drape placed over the foam paid, the drape being adhered to the skin above and below the pad (Figure 9a). The lateral protective strips 104 and 105 are removed in turn from the drape and the assembly adhered to the skin (Figures 9(b) and 9(c). Finally, the spout 36 is connected to a tube 106 which is then connected to a source of suction, e.g. a pump as described in our above PCT application, in order to apply negative pressure to the wound. The suction head and drape assembly is shown in Figure 8, with the smooth surface 37 adhered to the drape, is conveniently packaged in an easily openable plastic bag or pouch, and sterilised for immediate use.

CLAIMS:-

1. A suction head for applying suction to a wound area which comprises a generally planar flange portion and a tubular connector piece on a first face for connecting a suction tube to an aperture through the flange portion to the other face, said other face having projections defining flow channels for facilitating flow of fluids to said aperture.

2. A suction head as claimed in claim 1 which is combined with a surgical drape, the drape comprising a thin, flexible adhesive-coated plastics film, the tubular connector piece extending through an opening in the plastics film with the adhesive coating adhered to said first face of the flange portion.

3. A suction head and surgical drape combination as claimed in claim 2 in which the adhesive-coated film is strengthened with a second plastics film which is thicker or less flexible than said adhesive coated film.

4. A suction head and surgical drape combination as claimed in claim 2 or 3 wherein the adhesive coating on said flexible film is protected with a protective, releasable layer covering the area of the adhesive, said releasable layer comprising a separate strip protecting the adhesive coating in the vicinity of the suction head and said strip carrying a flap overlapping an adjacent portion of the releasable layer and constituting a handle to facilitate removal of said strip prior to use.

5. An assembly for use with a source of suction for stimulating healing of wounds which comprises a foam pad comprising an open-celled flexible polymer foam and a suction head and drape as claimed in claim 4

6. A surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the

adhesive coating, the drape having an aperture through at least the strengthening film and adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries at least one flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.

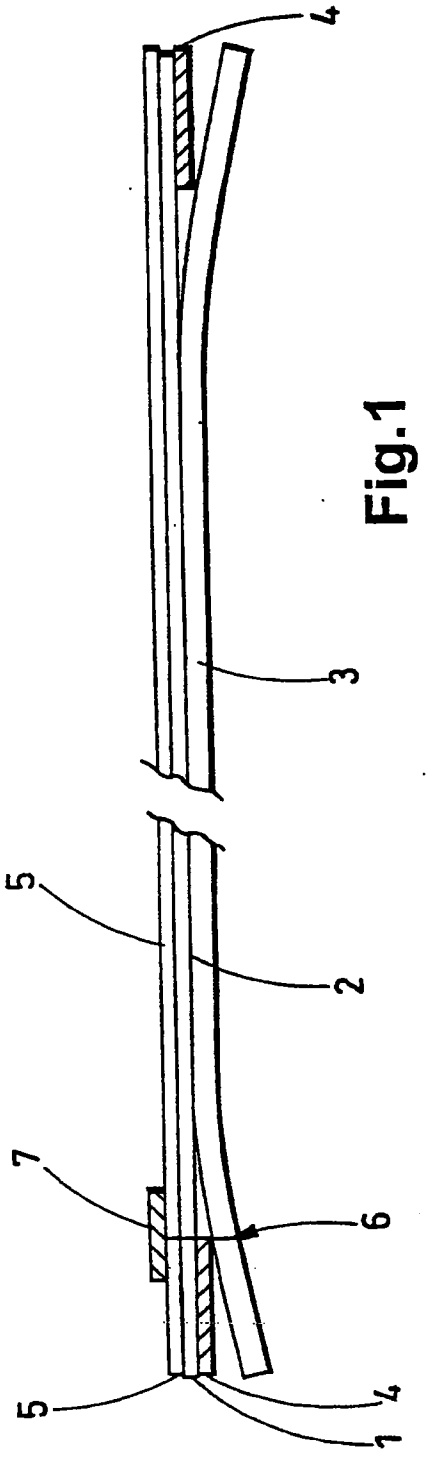


Fig.1

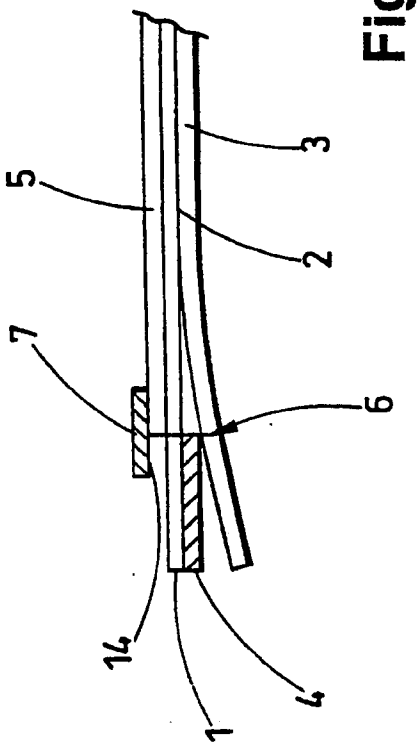


Fig. 2


Fig. 3

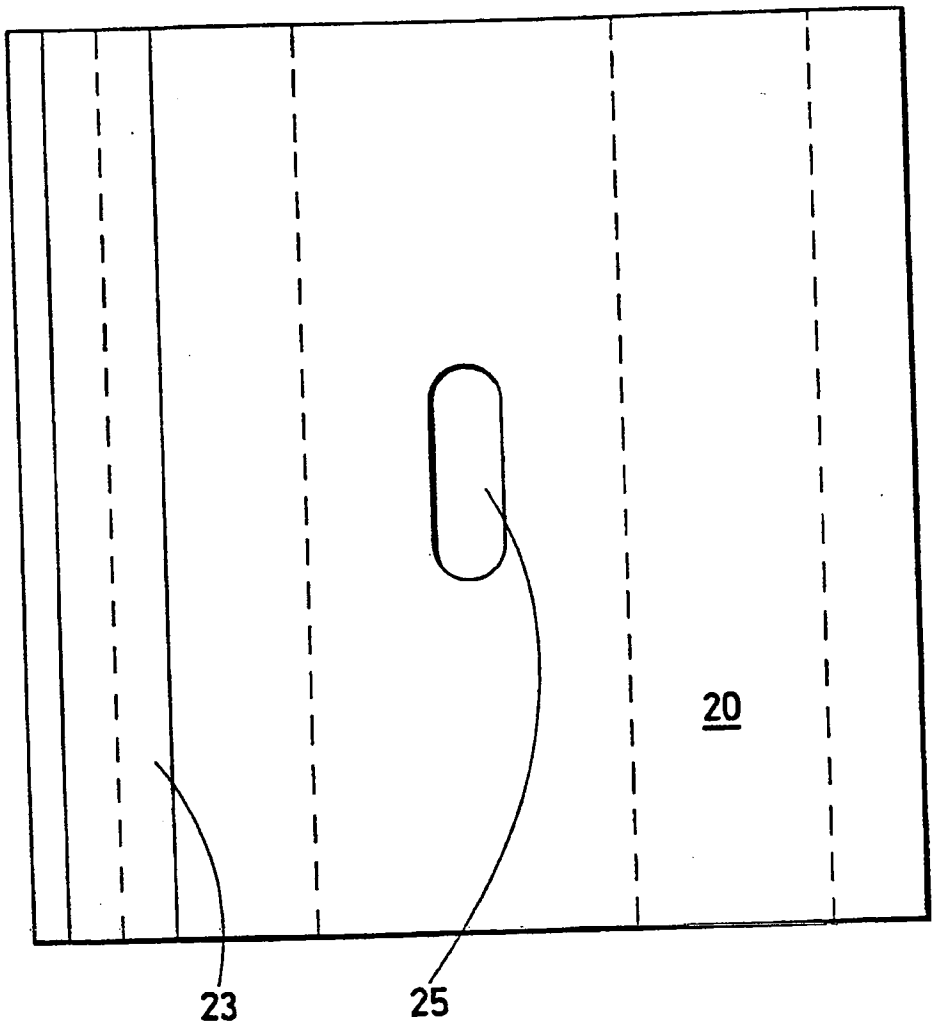


Fig. 4

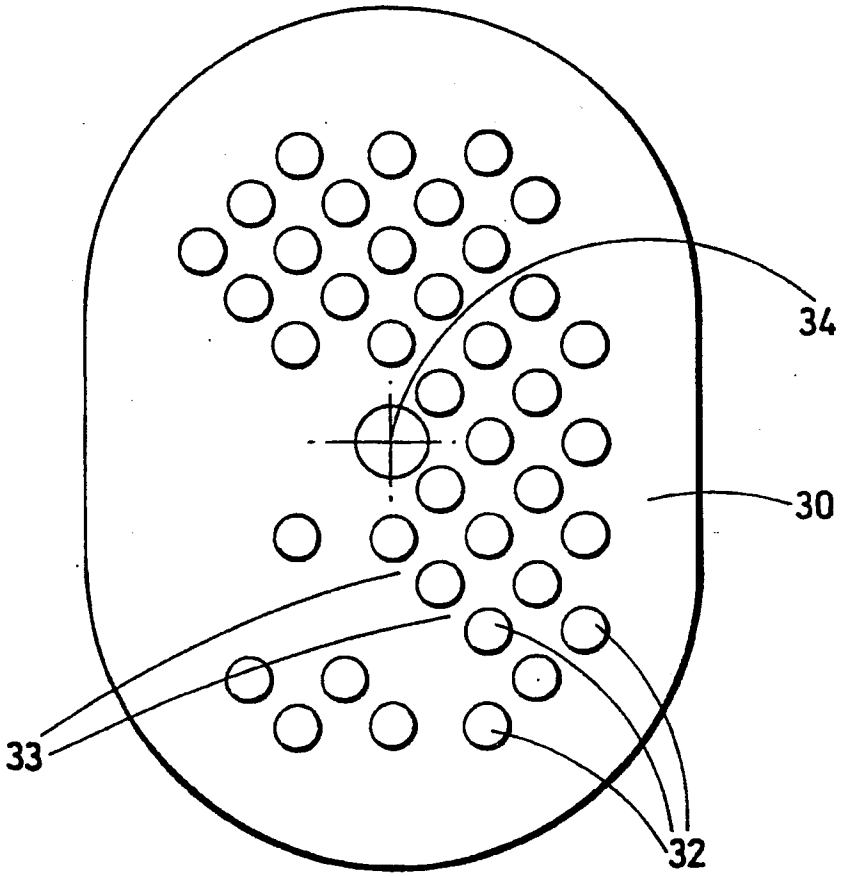


Fig. 5

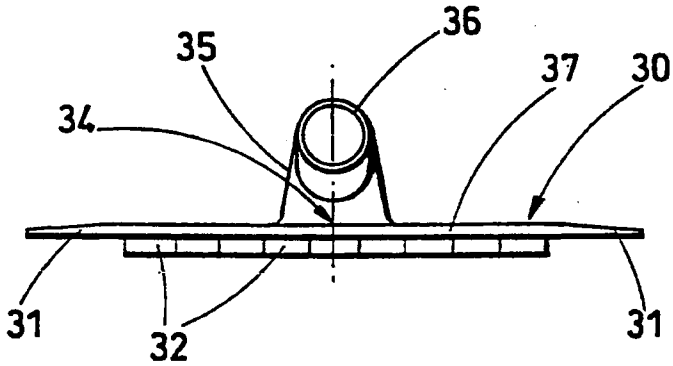


Fig. 6

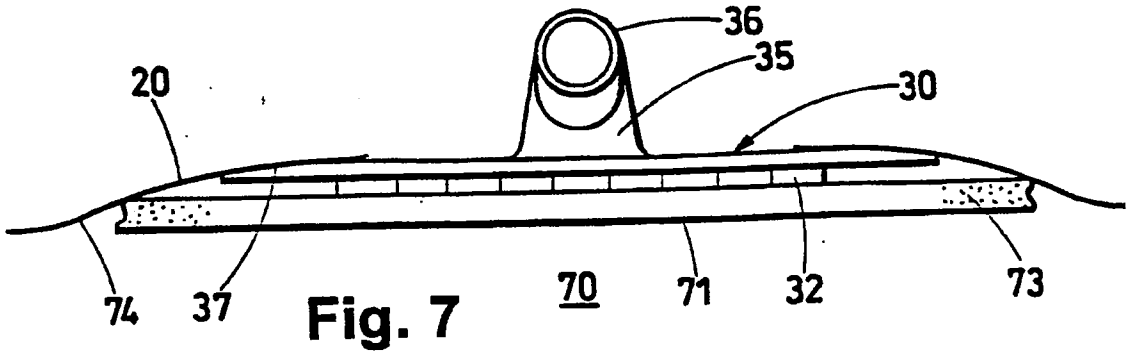


Fig. 7

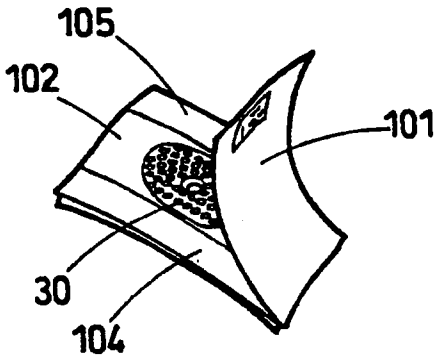


Fig. 8

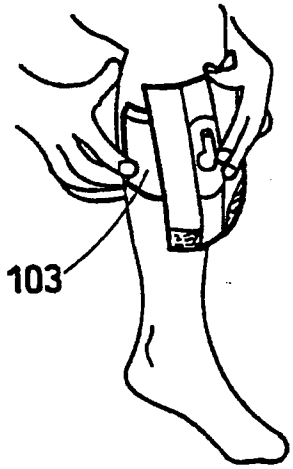


Fig. 9a

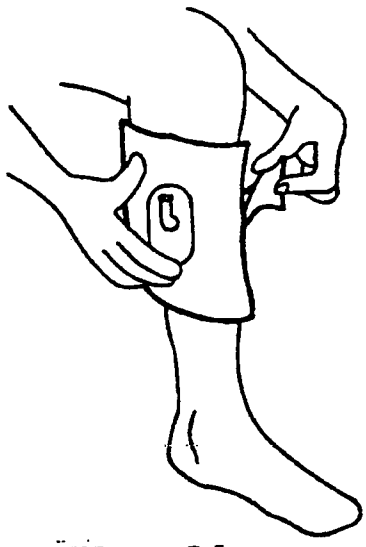

Fig. 9b

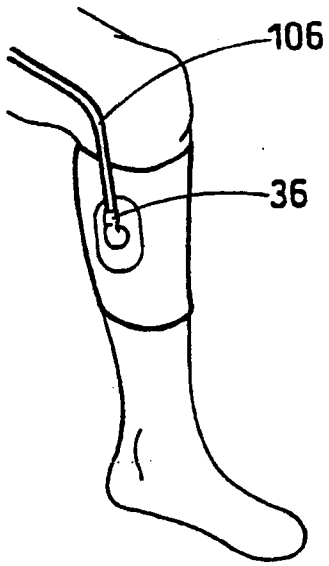


Fig. 9c

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 98/02713

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 19/08
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61F, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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"E" erlier document but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
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"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 10 December 1998 | 08. 01. 1999 |
| Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. ( + 31-70) 340-2040, Tx. 31 651 epo nl, Fax: ( + 31-70) 340-3016 | Authorized officer INGRID FALK |

SA 205392

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Information on patent family members

03/11/98

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